



Health and  
Wellness

Santé et  
Mieux-être



## Chief Public Health Office Policy

### Health Promotion Unit

Title:	<b>PEI Smoking Cessation Pharmacy Program</b>	Monitoring:
Chapter:		Draft Date: <b>December 1, 2024</b>
Section:	<b>Health Promotion</b>	Effective Date:
Subsection:	<b>Tobacco Control</b>	Revision Date:
Reference #:		Next Review:

Approving Authority: \_\_\_\_\_

Authorized Signature: \_\_\_\_\_

<b>Record of Decision</b>	Approving Body: <b>CPHO Management</b>
	Agenda #:
	Minute #:
	Meeting Date:
	Next Review:

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## 1.0 POLICY

- 1.1. The *PEI Smoking Cessation Program* covers 100% of the cost of smoking cessation products for eligible PEI residents who wish to stop smoking, vaping or using other tobacco products.

## 2.0 DEFINITIONS

- 2.1. **Age of Consent** means that the individual is considered legally competent to make decisions about their own healthcare, including consenting to treatments, without the need for permission from a parent or guardian.
- 2.2. **Moderate to severe nicotine addiction** refers to a high level of dependence on nicotine, characterized by intense cravings, increased tolerance, and withdrawal symptoms. Individuals at this level often struggle to reduce or quit smoking on their own and may find it difficult to do so without the support of an NRT.
- 2.3. **Nicotine** is a highly addictive, toxic substance that is the chief active ingredient in tobacco. It acts as a stimulant in small doses, but in larger amounts it is considered a poison and commonly used as an insecticide.
- 2.4. **Nicotine Replacement Therapies** are a type of treatment that uses special products to give small, steady doses of nicotine to help stop cravings and relieve symptoms that occur when someone is trying to quit smoking. These products include nicotine gum, inhaler, mouth spray, lozenges, and patches. They are available without a prescription and do not contain any of the other chemicals found in tobacco products.
- 2.5. **Pharmacotherapy** means the use of medication for smoking cessation; can be in the form of non-prescription nicotine replacement therapies or prescription drugs.

## 3.0 PURPOSE

This policy outlines the implementation of the *PEI Smoking Cessation Pharmacy Program* within community pharmacies.

## 4.0 BACKGROUND

- 4.1. Tobacco use is the number one preventable cause of illness and death in Prince Edward Island.
- 4.2. Tobacco use is a significant modifiable risk factor for five of the leading causes of morbidity and mortality in PEI (heart disease, stroke, respiratory disease, diabetes and cancer) and results in a significant burden on the healthcare system.
- 4.3. Tobacco use is higher among Island residents with poor social determinants of health such as low income, low education, and poor mental health.
- 4.4. Island residents who smoke repeatedly try to quit, but only 5-11% of quit attempts are successful without cessation support.
- 4.5. Tobacco cessation support programs are among the most cost-effective medical interventions available today. A combination of pharmacotherapy and counseling has been proven to almost triple the odds of quitting successfully, versus the use of either one alone.
- 4.6. The cost of pharmacotherapy, and access to cessation support counseling programs, are common barriers to cessation.
- 4.7. The publicly funded Universal PEI Smoking Cessation Program is a key component of a comprehensive tobacco control strategy, encompassing protection, prevention, and cessation efforts.

## 5.0 APPLICATION

### 5.1. Overview

- 5.1.1. The *PEI Smoking Cessation Program* helps PEI residents who wish to stop smoking, vaping or using other tobacco products by covering 100% of the cost of Nicotine Replacement Therapy (NRT) products (i.e., nicotine gum, lozenges, patches, spray and inhaler) and specific smoking cessation prescription drugs.

### 5.2. Eligibility

- 5.2.1. Coverage is available to all PEI residents' who smoke, vape or use other nicotine products and hold an active provincial health card.

### 5.3. Enrollment Process

Enrollment is facilitated through the following pathways:

- 5.3.1. **Healthcare Settings:** Enrollment is facilitated by trained Ottawa Model for Smoking Cessation (OMSC) Registered Nurses (RNs) or Respiratory Therapists (RTs) in Primary Care Networks, the Cancer Treatment Centre, Lennox Island, and Acute Care settings. Participants complete the Smoking Cessation Program Consultation Form and Intake Form, with consent documented in the Electronic Medical Record System.

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- 5.3.2. **Community Pharmacy:** Enrollment is facilitated by trained smoking cessation pharmacists in community pharmacies. Participants complete the Smoking Cessation Program Consultation Form and Intake Form, with consent documented in the Population Health Data Management System, managed by the Chief Public Health Office.
- 5.4. **Assessing NRT Prescriptions for Youth**  
For individuals under 18 who are moderately or severely addicted to nicotine and motivated to quit, prescribing Nicotine Replacement Therapy (NRT) may be considered when the benefits outweigh the risks.
  - 5.4.1. **Clinical Judgment:** The prescribing of NRT is at the discretion of the healthcare provider, who must assess the individual's nicotine dependence, readiness to quit, and any potential health risks or contraindications related to NRT.
  - 5.4.2. **Informed Consent:** Youth under 18 are assumed to be capable of providing informed consent unless proven otherwise. Healthcare providers must ensure the youth fully understands the potential benefits, risks, and alternatives to NRT.
- 5.5. **Provider Responsibility:** When prescribing NRT to youth, healthcare providers must consider the patient's readiness to quit, their understanding of the treatment process, and provide ongoing monitoring and support to ensure the therapy is effective and well-tolerated.

## 6.0 PROCEDURES

### 6.1. Smoking Cessation Products Covered

- 6.1.1. The Smoking Cessation Program covers two types of smoking cessation products: Prescription smoking cessation drugs Bupropion (brand name Zyban®) and Varenicline (generic brands), and specific non-prescription nicotine replacement therapy (NRT) products (see APPENDIX B).

### 6.2. Duration and Frequency of Coverage

- 6.2.1. Coverage is limited to a single continuous course of treatment, at a minimum of 6 weeks (42 days) to a maximum of 18 weeks (126 days) of one eligible smoking cessation product (i.e., one course of a nicotine replacement therapy, or bupropion, or varenicline) for the current enrollment year.
- 6.2.2. The 6 to 18 weeks (42 days-126 days) of coverage begins on the first day of enrollment in the smoking cessation program. All eligible fills of the product must be dispensed within the special authorization period of 22 weeks (42

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to 154 days of the first fill). Program billing expires 22 weeks after program initiation.

- 6.2.3. Coverage year runs from the first day of enrollment through to the following year. Unused coverage from one enrollment year cannot be carried into the next enrollment year.
- 6.2.4. Starting one year from the date of enrollment: A new coverage year begins; coverage is reset to 42 to 126 consecutive days (6-18 weeks) for the new year.
- 6.2.5. Patients who have not received all their eligible product fills for a course of treatment by the last day of their enrollment period cannot complete their entire course of treatment.
- 6.2.6. Patients who have not received all their product fills for a course of treatment due to illness may re-enroll in the program and access their new 42 to 126 days of coverage.
- 6.2.7. The pack size of a particular product may result in minor overruns in treatment duration, and these small overruns are deemed acceptable.

### **6.3. Supplemental Coverage or Changes in Coverage**

- 6.3.1. Individuals who want to supplement the coverage available through this Program are expected to cover the costs themselves or through their extended health plans.
- 6.3.2. During a course of treatment, patients may switch between one dosage strength to another only when picking up their fills covered for the course of treatment.
- 6.3.3. Patients are permitted to switch the course of treatment (e.g., switch from one type of nicotine replacement therapy to one of the prescription smoking cessation medications or vice versa) at the 14-day follow-up appointment or within 30 days of starting their initial treatment with a smoking cessation provider.
- 6.3.4. All Program policy limitations with respect to maximum days' supply, dispensing intervals and dispensing fees continue to apply regardless of changes in product or strength.

### **6.4. Travel Supply**

- 6.4.1. Eligible individuals who have expressed their intent to travel outside of PEI may qualify for a travel supply, in accordance with the PEI Pharmacare Smoking Cessation Program Travel Supply Policy.
- 6.4.2. Individuals must visit a PEI community pharmacy to request a travel supply of medication. Coverage is limited to a single continuous course of treatment, ranging from a minimum of 42 days to a maximum of 126 days

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for one eligible smoking cessation product. The duration depends on the prescribed medication and the treatment plan.

- 6.4.3. Clients must be stabilized on their medications for at least 28 days of regular use before a travel supply can be filled at a community pharmacy.
- 6.4.4. Eligible clients are required to sign a Travel Declaration form at their community pharmacy.
- 6.4.5. Clients who request and receive more than the recognized Pharmacare maximum days' supply will be responsible for the cost of any excess supply exceeding that limit.

**6.5. Nicotine Replacement Therapies: Products Covered and Claims**

- 6.5.1. Eligible individuals receive no-cost (100%) coverage of the designated NRT purchased at a pharmacy in the same manner as prescription drugs. Patients do not need a prescription for NRT coverage.
- 6.5.2. A pharmacy must retain a copy of the Smoking Cessation Intake Form. Claims without a copy of the signed intake form or claims submitted outside the parameters (quantity and product) of the intake form are subject to recovery upon audit.
- 6.5.3. Program coverage of nicotine replacement therapies is limited to the products in the list of Eligible Smoking Cessation Products (see APPENDIX B).

**6.6. Maximum Days' Supply Per Fill and Dispensing Interval**

**6.6.1. Nicotine Patches**

Eligible nicotine patches are to be dispensed in four-week (28 day) intervals. The Program limits coverage of eligible generic brand nicotine patches to a maximum 28-day supply. Over the total 6-18 weeks (42 to 126 day) course of treatment, patients are eligible for coverage of up to 42 to 210 NRT patches (7 patches in each box). This quantity is based on the maximum dosing specified in the product monograph.

**6.6.2. Nicotine Gum**

Over the total course of treatment, patients are eligible for up to 945 pieces of NRT gum (supplied as 9 boxes with 105 pieces in each box). This quantity is based on the maximum dosing specified in the product monograph. On average, most patients need 3 boxes of NRT gum (total 315 pieces) every 28 days.

**6.6.3. Nicotine Lozenges**

Over the total 12-week (84-day) course of treatment, patients are eligible for up to 792 pieces of NRT lozenge. This quantity is based on the dosing

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range specified in the product monograph. On average, most patients need 3 bottles of NRT lozenge (total 264 lozenges) every 28 days.

**6.6.4. Nicotine Inhaler**

Over the total 12-week (84-day) course of treatment, patients are eligible for up to 1008 cartridges (supplied as 24 boxes with 42 cartridges in each box).

**6.6.5 Nicotine Mouth Spray**

Over the total 12-week (84-day) course of treatment, patients are eligible for up to 420mls (supplied as 14 boxes with 1-30ml inhaler in each box).

**6.7. Dispensing Fees**

6.7.1. Community pharmacies are reimbursed for a dispensing fee up to the Pharmacare maximum for the dispensing of eligible NRTs.

6.7.2. Pharmacare covers the dispensing fee for up to six dispenses per patient per course of treatment with one of the designated NRTs. Pharmacare cannot control the quantity of dispenses; the number of dispenses cannot be set as a limit.

6.7.3. The number of dispenses of a treatment drug is based on the quantity for the day's supply. Pharmacists should ensure all dispensing is within the authorized period (amount of days' supply) per the program eligibility.

**6.8. Application of the Full Payment Policy**

6.8.1. Pharmacies may not charge individuals directly for any amount in excess of the Pharmacare paid for nicotine replacement therapy claims covered under the Program.

**6.9. Returns or Exchanges of Nicotine Replacement Therapies (NRTs)**

6.9.1. Patients cannot return any unused products for exchange, reimbursement or credit.

**6.10. Smoking Cessation Drugs**

6.10.1. Coverage is available to all individuals who smoke (and users of other tobacco products) who are residents of PEI and have a valid provincial health card.

6.10.2. Coverage is available to all individuals who smoke and vape (and users of other nicotine products) who are residents of PEI and have a valid provincial health card.

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6.10.3. Eligible prescription smoking cessation drugs are to be dispensed in four-week (28 day) intervals. Pharmacare covers a maximum 28-day supply of eligible prescription smoking cessation drugs.

**6.11. Products covered**

6.11.1. See Appendix B

6.11.2. Of the different versions of bupropion, PharmaCare covers only Zyban® for smoking cessation. Wellbutrin®, Wellbutrin XL® and generic bupropion are not covered as smoking cessation drugs.

6.11.3. To ensure the prescription is for the version of bupropion eligible for PEI Smoking Cessation Program coverage, prescribers are to indicate on the prescription: the brand name Zyban®, the prescription is for “smoking cessation,” and “no substitutions.”

6.11.4. Pharmacare only fully covers generic versions of varenicline.

6.11.5. Patients require a prescription to be eligible for coverage.

6.11.6. Individuals covered by the PEI Smoking Cessation Program for eligible prescription smoking cessation drug are not eligible for coverage of nicotine replacement therapies in the same 12-month period.

**6.12. Procedures for Pharmacists**

6.11.2 Pharmacists are required to complete a Smoking Cessation Program Consultation Form (Initial Assessment) along with the program intake form (Action Plan) for their patients using the Population Health Data Management System (PHDMS).

6.11.3 New intake forms will be prepared for patients if there is a change to the therapeutic approach (product, quantity and duration).

6.11.4 Review the patient’s medication history in DIS to determine if the patient has already received prior Pharmacare coverage for a course of treatment with a smoking cessation product (nicotine replacement therapy, bupropion or varenicline) in the current enrollment year or has used up their coverage for a current course of treatment.

6.11.5 Complete documentation, including the patient’s history of tobacco use, assess the patient's readiness to quit smoking or vaping, and submit the program intake form to Pharmacare for reimbursement.

6.11.6 Pharmacists are reimbursed for one (1) initial assessment claim per 12 months (see APPENDIX A).

6.11.7 Follow-up assessments are limited to three (3) follow-up claims per year, with a minimum of seven (7) days between each claim (see APPENDIX A).

**6.12 Submitting Claims for Nicotine Replacement Therapies (NRTs)**

6.12.2 An intake form must be presented and signed by the SCP intake provider



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(e.g., RN/RT/Pharmacist) for reimbursement of over-the-counter NRT products. New intake forms will be prepared for patients if there is a change to the therapeutic approach (product, quantity and duration). The pharmacy should only submit claims based on the most recent intake form received.

6.12.3 In separate yearly files, file the intake form by patient name, then chronologically. Claims without an intake form or with only one signature are subject to recovery upon audit.

6.12.4 Enter the fill as a new prescription (not a refill).

6.12.5 Enter the appropriate product NPN.

6.12.6 Enter the SCP prescriber code as 499 to identify the prescriber when submitting reimbursement claims of over-the-counter NRT products to PEI Pharmacare.

6.12.7 Enter the number of units dispensed in the Dispensed Quantity field (i.e., the number of pieces of gum, lozenges, or patches).

6.12.8 Enter the drug cost and dispensing fee. Do not add GST to either the drug cost or the dispensing fee.

#### 6.13 **Submitting Claims for Prescription Smoking Cessation Drugs**

6.13.2 Confirm that the prescribed drug is eligible for *PEI Smoking Cessation Program* coverage. Prescriptions for varenicline (Champix® and generics) can be written in the usual fashion. Prescriptions for bupropion must specify the Zyban® brand of bupropion and indicate the prescription is for smoking cessation.

#### 6.14 **Program Evaluation**

6.14.2 The PEI Smoking Cessation Pharmacy Program will undergo an evaluation that is distinct from the broader *PEI Smoking Cessation Program*. This separate evaluation aims to analyze the program's effectiveness in reaching participants and evaluate its cost-effectiveness.

## 7.0 **CROSS REFERENCE**

7.1. PEI Pharmacy Act

7.2. PEI Pharmacy Act Regulations

## Template Definitions

**TITLE:** Title by which the Policy will be officially referred to and indexed in the manual.

**CHAPTER:** Indicates the chapter under which the policy falls in the Policy Manual.

**SECTION:** Indicates the primary section under which the policy falls in the Policy Manual.

**SUBSECTION:** Indicates the subsection under which the policy falls in the Policy Manual.

**REFERENCE NUMBER:** The number assigned to a policy by which it is indexed in the manual. This number is meant to assist readers to find and access policies in the manual.

**MONITORING:** The position assigned responsibility for monitoring the policy.

**DRAFT DATE:** The date the draft policy was submitted to the approving body.

**APPROVED DATE:** The date the policy was approved.

**EFFECTIVE DATE:** The date the policy is to take effect.

**REVIEW DATE:** The date the policy was last reviewed.

**NEXT REVIEW:** The next date the policy is to be reviewed.

**APPROVING AUTHORITY:** The executive or administrative authority under which the policy was established.

**AUTHORIZED SIGNATURE:** The legislative or executive authority under which the policy was approved. This signature will be either the Minister of Health and Wellness or the Deputy Minister of Health and Wellness.

**POLICY STATEMENT:** A concise statement of rules, expectations, and requirements for a prescribed situation.

**DEFINITIONS:** Definitions of key words used throughout the policy.

**PURPOSE (Optional):** The purpose identifies the intent of the policy, the situation(s) and people to which it applies, and the desired outcomes.

**BACKGROUND (Optional):** The background provides contextual information which can help the reader understand the need for the policy and its intent. The Background should help inform appropriate use and application of the policy.

**APPLICATION:** Identify entities or people to which the policy does or does not apply to.

**PROCEDURES:** Procedures provide detailed specification of steps and processes to be performed in order to implement or comply with a policy.

**GUIDELINES:** Guidelines are suggested good practice for implementing policies and / or procedures.

**KEY SEARCH WORDS:** Key words help readers find and access policies in the manual.

**CROSS REFERENCE:** List of legislation, regulations, government and departmental policies, agreements and standards with which the policy needs to comply or on the basis of which the policy was necessitated.

**RECORD OF DECISION:** This section is for record keeping purposes and will be filled in by the executive or administrative authority under which the policy was established.

## Appendix A: PseudoDIN (PDIN) for Smoking Cessation Assessments

Service Name	Service Description	Pharmacare PDIN	Billing Parameters	Fee
SCP Assessment	Initial Assessment - Nicotine Dependence	93899797	Max per year: 1	\$25
SCP Follow-up Assessment	Follow-up - Nicotine Dependence	93899724	Max per year: 3	\$25

## Appendix B: Eligible Smoking Cessation Products

Generic (Brand) Name	Drug Identification Number (DIN) or Billing DIN	Billing Parameters for each DIN (Program: Max Days Supply: 28)
Bupropion (Zyban®) Tablet 150mg	02238441	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 249 (18 weeks) Max QTY Days: 365
Varenicline 0.5 mg	02291177 (Champix®) 02419882 (APO) 02426226 (TEVA)	Min Days Supply: 7 Max Days Supply: 28 Max QTY per Period: 252 Max QTY Days: 365
Varenicline 1 mg continuation pack	02291185 (Champix®) 02419890 (APO) 02426234 (TEVA)	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 238 Max QTY Days: 365
Varenicline 0.5/1 mg starter kit	02298309 (Champix®) 02435675 (APO) 02426781 (TEVA)	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 53 Max QTY Days: 365
Nicotine 2 mg Gum	00999976 (Billing DIN)	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 945 pieces Max QTY Days: 365
Nicotine 4 mg Gum	00999980 (Billing DIN)	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 945 pieces Max QTY Days: 365
Thrive® 1 mg Lozenge	80007461	Min Days Supply: 14 Max Days Supply: 28

		Max QTY per Period: 792 pieces Max QTY Days: 365
Thrive® 2 mg Lozenge	80007464	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 792 pieces Max QTY Days: 365
Nicorette® 2 mg Lozenge	02247347	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 792 pieces Max QTY Days: 365
Nicorette® 4 mg Lozenge	02247348	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 792 pieces Max QTY Days: 365
Nicotine Step 1 (21 mg) Patch	00999975 (Billing DIN)	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 140 patches Max QTY Days: 365
Nicotine Step 2 (14 mg) Patch	00999974 (Billing DIN)	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 56 patches Max QTY Days: 365
Nicotine Step 3 (7 mg) Patch	00999973 (Billing DIN)	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 56 patches Max QTY Days: 365
Nicorette® (10 mg) Inhaler	02241742	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 1008 cartridges Max QTY Days: 365
Nic-Hit (1 mg) Spray	80054636	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 420 mL Max QTY Days: 365
Nic-Hit (2 mg) Spray	80060452	Min Days Supply: 14 Max Days Supply: 28 Max QTY per Period: 420 mL Max QTY Days: 365