


Medical Directive

Title: **Prescription Medications for Smoking Cessation for Adults > 18 years old** **Assigned Number:** **015**

Activation Date: **July 1, 2011** **Review due by:** **December 2023**

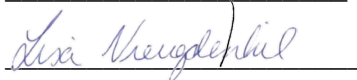
Approval Signature & Date

Medical Director:



Date Reviewed: January 13, 2022

Clinical Services Director:



Date Reviewed: January 13, 2022

Order and/or Delegated Procedure:

Appendix Attached: ☐ Yes ☒ No
Title:

Initiation and renewal of smoking cessation products by Registered Pharmacists and Registered Nurses/ Registered Practical Nurses for patients > 18 years old.

Recipient Patients:

Appendix Attached: ☒ Yes ☐ No
Title:

All active patients of Thames Valley Family Health Team physicians, identified on the Authorizer Approval Form, who require medications to assist in smoking cessation.

Authorized Implementers:

Appendix Attached: ☒ Yes ☐ No
Title:

Thames Valley Family Health Team Registered Pharmacists and Registered Nurses/Registered Practical Nurses (RPh/RN/RPN) *

- * The implementing RPh and RN/RPNs must receive orientation from the Educator with regards to the task. The RPh or RN/RPN's must sign the Implementer Performance Readiness Form in HR Downloads after successful completion of the orientation indicating acceptance of this medical directive.

Indications:	Appendix Attached: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Title: Appendix 13 - List of Medications for Smoking Cessation with Detailed Indications/ Contraindications
<ol style="list-style-type: none"> 1. Verbal consent received from the patient for the implementing RPh or RN/RPN to implement this directive. 2. Medication is offered as a smoking cessation aid option in conjunction with behavioural modification strategies and support. 3. Patient willing and able to follow up with RPh or RN/RPN on a predetermined date. 	
Contraindications: <ol style="list-style-type: none"> 1. No verbal consent from the patient for RPh or RN/RPN to implement this medical directive. 2. Patient is < 18 years old. 3. Patient is pregnant or lactating. 4. Ongoing substance use disorder and/or withdrawal from abrupt discontinuation of substance use 5. Specific contraindications for each product as outlined in List of Medications for Smoking Cessation with Detailed Indications/Contraindications (Appendix 13). 	
Consent:	Appendix Attached: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Title:
<ol style="list-style-type: none"> 1. Patients of Thames Valley Family Health Team family physicians. 2. RPh or RN/RPN obtains verbal consent prior to the implementation of care. 	

Guidelines for Implementing the Order/ Procedure:	Appendix Attached: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Title: Appendix 13 - List of Prescription Medications Appendix 14 - The Fagerstrom Test for Nicotine Dependence Appendix 15 - Nicotine Replacement Dosing Information Appendix 16 - Decision Tree to address Nicotine Withdrawal: Increasing dosage beyond 21mg patch
<ol style="list-style-type: none"> 1. Assess patient's readiness to change smoking habits and history of smoking cessation including past attempts. Assessments completed by other members of the Family Health Team may be used. 2. If patient is in preparation/action stage set Stop Smoking Date. 3. Assess Nicotine Addiction using Revised Fagerstrom Nicotine Addiction Scale (Appendix 14): <ul style="list-style-type: none"> • If rating is >3/10 review Pharmaceutical Options, including Nicotine Replacement Therapy (NRT) • If rating is <3/10 pt may not require medication 4. Assess for any contraindications to Zyban (bupropion), Champix (varenicline), NRT (nicotine replacement therapy) (Appendix 15) and precautions (Appendix 13) 5. Ensure other smoking cessation strategies (behavior modification and supportive) are in place for Stop Smoking Date 6. Arrange follow up appointment as appropriate if patient requests. 7. Order appropriate medication according to List of Medications for Smoking Cessation (Appendix 13), as per usual standard with the family physician's name on the prescription. 	
Documentation and Communication:	Appendix Attached: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Title:
<ol style="list-style-type: none"> 1. Documentation in the patient's medical record needs to include name and number of the directive, name of the implementer (including credential), and name of the physician/authorizer responsible for the directive and patient. 2. Information regarding implementation of the procedure and the patient's response should be documented, in the patient's medical record, in accordance with standard documentation practice. 3. Standard documentation is recommended for prescriptions, requisitions, and requests for consultation. * <p>* <i>Potter, P.A. & Perry, A.G. (2006). Fundamentals of Nursing. St. Louis: Mosby.</i> <i>College of Nurses of Ontario (2008). CNO Practice Standard: Documentation</i></p>	

Review and Quality Monitoring Guidelines:	Appendix Attached: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Title:
<ol style="list-style-type: none"> 1. The Directive remains in force until and unless amendment occurs. Review will occur biennially. In the case the Medical Director identifies the need to change the Medical Directive, at least one TVFHT member of the implementing discipline will be consulted. 2. At any such time that issues related to the use of this directive are identified, the team must act upon the concerns immediately by identifying these concerns to the Medical Director. The Medical Director will review these concerns and consult with at least one TVFHT member of the implementing disciplines, before necessary changes are made. 3. If new information becomes available between routine renewals, and particularly if this new information has implications for unexpected outcomes, the directive will be reviewed by the Medical Director and a minimum of one implementing RN/RPN or RPh. 	
Approving Physician(s)/Authorizer(s):	Appendix Attached: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Title:
Authorizer Approval Form	

Appendix 13 - List of Prescription Medications for Smoking Cessation with Detailed Indications/Contraindications

Prescribing: Zyban (bupropion)

- If choosing Zyban prescribe 150mg daily X3 days (starting 1 week prior to stop smoking date), then increase to 150mg BID (to stop smoking between day 7 and 10).
- Renal Dysfunction: Use with caution; manufacturer's labeling suggests a reduction in dose and/or frequency be considered but does not provide specific dosing recommendations
- Advise patient to not take Zyban any closer than 8 hours apart due to increased seizure risk
- Ensure other smoking cessation strategies (behaviour modification and supportive) are in place for Stop Smoking Date
- With close supervision, therapy may continue 3-6 months. If within 3 months patient has not stopped smoking, stop therapy, and offer alternatives, setting another stop date with support
- Can be used with NRT if strong physical component to nicotine addiction (moderate to high Fagerstrom score)

Contraindications:

- Known hypersensitivity to Bupropion
- Already being treated with Wellbutrin SR (bupropion), Wellbutrin XL or bupropion for depression
- Current treatment with MAO inhibitors (Isocarboxazid; Linezolid; Methylene Blue; Moclobemide; Phenelzine; Rasagiline; Safinamide; Selegiline; Tranylcypromine), Thioridazine (within 14 days), St. John's Wort
- Pregnant (1st Trimester)
- Lactation
- Under 18 years old
- Caution within recent MI, unstable heart disease, uncontrolled hypertension, risk of seizure (e.g., history of head trauma)
- Caution with medications that lower seizure threshold - e.g., antipsychotic, antidepressants, Lithium, Amantadine, Theophylline, systemic steroids, Quinolone antibiotics and antimalarials, OTC stimulants or anorectics, diabetes treated with oral hypoglycemic agents or insulin
- Caution with medical conditions that lower seizure threshold:
 - History of a seizure disorder
 - History of eating disorder- bulimia or anorexia nervosa
 - Impaired liver or kidney function (eGFR < 60 mL/min)
 - Undergoing abrupt discontinuation of ethanol or sedatives including anticonvulsants, barbiturates, or benzodiazepines

Precautions:

- Dosing considerations:
 - Do not administer doses less than 8 hours apart (increase seizure threshold)
 - Daily total dose may not exceed 300mg
 - Insomnia may be minimized by avoiding bedtime doses (I.e., last dose by 1800)
- Smoking cessation with or without varenicline may alter pharmacodynamics or pharmacokinetics of some drugs for which dosage adjustment may be necessary (including but not limited to theophylline, clozapine, warfarin and insulin). Smoking cessation may result in increased plasma levels of CYP 1A2 substrates. The prescriber needs to be notified ASAP of smoking cessation if the patient is on any of the above medications.

Prescribing: Champix (varenicline)

- Prescribe 0.5 mg orally once daily for days 1-3 (starting 1-2 weeks prior to stop smoking date), then increase to 0.5 mg orally twice daily for 4-7 days, then increase to 1 mg orally twice daily on day 8 to end of treatment.
- Advise patients to follow-up with their provider if they experience side effects. The provider may counsel the patient to reduce their dose to 0.5 mg 1-2 times daily to improve tolerability.
- Patients to be advised to set a date to stop smoking
- Dose to be adjusted in patients with severe renal impairment ($\text{CrCl} < 30 \text{ mL/min}$).
 - $\text{CrCl} < 30 \text{ mL/minute}$: Initial: 0.5 mg once daily; maximum maintenance dose: 0.5 mg twice daily
- Duration of treatment is 12 weeks. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment with Champix may be considered
- Ensure other smoking cessation strategies (behaviour modification and supportive) are in place for Stop Smoking Date

Contraindications:

- Patients who are hypersensitive to varenicline or to any ingredient in the formulation or component of the container
- Patients < 18 years of age
- Pregnancy or lactation

Precautions:

- Total daily dose may not exceed 2mg
- The concomitant use of NRT may result in increase in adverse reactions including nausea, headache, vomiting, dizziness, dyspepsia, and fatigue
- Smoking cessation with or without varenicline may alter pharmacodynamics or pharmacokinetics of some drugs for which dosage adjustment may be necessary (including but not limited to theophylline, clozapine, warfarin and insulin). Smoking cessation may result in increased plasma levels of CYP 1A2 substrates. The prescriber needs to be notified ASAP of smoking cessation if the patient is on any of the above medications
- Caution patient -may cause mild to moderate nausea, most often transient but for some, may persist over several months
- May cause dizziness or somnolence

Prescribing: Nicotine Replacement Therapy (NRT)

- Patients will be offered the choice of NRT products available
- Product recommendations, including contraindications and dosages, based on **Appendix 15- Table 1- Nicotine Replacement Dosing Information**

Precautions:

- Caution patients if they continue to smoke while using NRT -may experience adverse effects due to peak nicotine levels higher than those experienced with smoking alone.
- Patients are asked to rotate the site of patch application daily to prevent/ minimize local irritation

Appendix 14 - The Fagerstrom Test for Nicotine Dependence

Score each of the following questions (the scores are given in brackets)

1. How soon after you wake up do you have your first cigarette?

- A. Within 5 minutes (3) B. 6-30 minutes (2)
C. 31-60 minutes (1) D. After 60 minutes (0)

2. Do you find it difficult to refrain from smoking in places where it is forbidden, e.g., in church, the library, the cinema, etc.?

- A. Yes (1) B. No (0)

3. Which cigarette would you hate most to give up?

- A. The first one in the morning (1) B. All others (0)

4. How many cigarettes do you smoke per day?

- A. 10 or fewer (0) B. 11-20 (1)
C. 21-30 (2) D. 31 or more (3)

5. Do you smoke more often during the first hours after waking than during the rest of the day?

- A. Yes (1) B. No (0)

6. Do you smoke even if you are so ill that you are in bed most of the day?

- A. Yes (1) B. No (0)

Now add up your score:

7 to 10 points = highly dependent on nicotine

4 to 6 points = moderately dependent on nicotine

less than 4 points = less dependent.

The higher your score, the more likely you are to have withdrawal symptoms if you give up smoking, and the withdrawal symptoms are likely to be stronger.

Appendix 15 - Nicotine Replacement Dosing Information

Medication/Dosage Nicotine Replacement Therapy:	Indications	Contraindications/Cautions	Max Dose/24h
<i>Nicotine Patch</i> <u>Can be given alone or in combination with nicotine gum and inhaler</u>			
Nicotine Patch (21mg)/24h	Smoking >10 cigarettes per day (CPD)	Contact hypersensitivity to the patch. Signs and symptoms of these may include erythema, pruritis, edema, hives, or generalized rash or urticaria. *Pregnancy, recent cerebrovascular event, immediately post MI, angina, life threatening arrhythmias	**42mg
Nicotine Patch (14mg)/24h	Smoking 7-14 CPD	As above	**42mg
Nicotine Patch (7mg)/24h	Less than 7 CPD or unable to tolerate higher doses of NRT	As above	**42mg
<i>Nicotine Gum</i> <u>Can be used alone or in combination with nicotine patch and inhaler</u>			
Nicotine Gum 4mg q 1h prn	Willing to learn the proper technique since the nicotine must be absorbed across the buccal mucosa.	Unable to chew gum Wears dentures immediately post MI, arrhythmias, angina, active TMJ dysfunction	20 pieces of Nicorette gum
Nicotine Gum 2mg q 1h prn	As above, use 2 - 4mg first, switch to 2mg if unable to tolerate 4mg gum- too strong, signs/symptoms of nicotine toxicity with 4mg gum (nausea, diaphoresis, irritated throat, etc.)	As above	20 pieces of Nicorette gum

Medication/Dosage Nicotine Replacement Therapy:	Indications	Contraindications/Cautions	Max Dose/24h
<i>Nicotine Inhaler</i> <i>Can be used alone or in combination with nicotine gum or patch</i>			
Nicotine Inhaler 10mg cartridge Q1h prn (delivers 4mg nicotine per cartridge)		Recent CVA, immediately post MI, angina, life threatening arrhythmias.	6 cartridges
<i>Nicotine Lozenge</i> <i>Can be used alone or in combination with nicotine gum, patch, or inhaler</i>			
Nicotine Lozenge 2mg Q 1-2 hrs. PRN	Unable to tolerate or use nicotine gum or inhaler	Recent CVA, immediately post MI, angina, life threatening arrhythmias.	15 nicotine lozenges per day
Nicotine Lozenge 4mg Q 1-2 hrs. PRN	Unable to tolerate or use nicotine gum or inhaler Use 4mg first, switch to 2mg if unable to tolerate 4mg lozenge Signs and symptoms of nicotine toxicity with 4mg lozenge (nausea, diaphoresis, irritated throat, etc.)	As above	15 nicotine lozenges per day

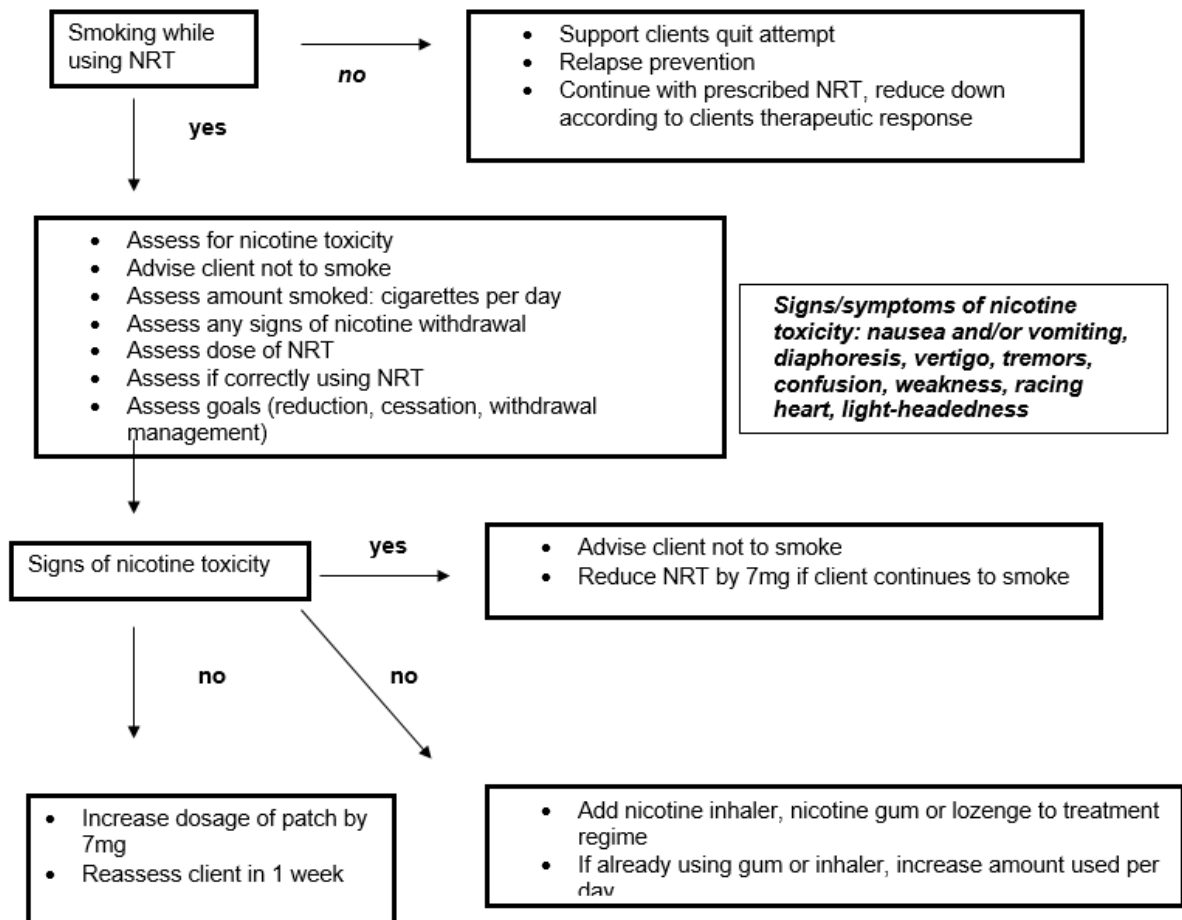
* Recent studies have shown that using NRT is safer than smoking. Any client who is pregnant or who has a history of heart disease, recent CVA or MI, or any arrhythmias should be initiated on NRT by a physician. The RN, RPN or Pharmacist can then continue these clients on NRT and reduce dosages accordingly. Any increase in dosage should be done by the physician.

** Clients can be titrated up to and including 42 mg patch dosage by the RN/RPN or Pharmacist (including in combination with PRN nicotine gum or inhaler). See Appendix 16 - DECISION TREE TO ADDRESS NICOTINE WITHDRAWAL: INCREASING DOSAGE BEYOND 21MG PATCH

NB If client experiences nausea or vomiting, diaphoresis, tremors, confusion, or weakness after using NRT, this could mean they are receiving too high a dose and the NRT product should be discontinued. Once the client's condition stabilizes, the RN/RPN or Pharmacist can try a lower dose and continue to monitor client closely for the above signs.



Appendix 16 - Decision Tree to Address Nicotine Withdrawal: Increasing Dosage Beyond 21 mg Patch



If client requires greater than 42mg dosage, refer client to see physician or nurse practitioner. The pharmacist or RN/RPN can then continue clients on dosages of 42mg or higher. Any additional increases beyond 42mg should be done by the physician or nurse practitioner.