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Interprofessional Primary Care Medical Directive for Smoking Cessation

Adapted from Federation of Health Regulatory Colleges of Ontario Template Last Updated September 14, 2017

Title: Prescription of Varenicline (CHAMPIX)

Number: _____

Activation Date: _____

Review Due By: _____

Appendix A Attached: **Yes X** **No** **Title**: Varenicline Dosing Guidelines

Directive Order:

Initiate, adjust, renew, or discontinue varenicline by authorized regulated health professional(s) working within the smoking cessation program with or without prior consultation with the physician.

Varenicline dosing is as follows

- Start at a minimum of 1 week before planned quite date
- Varenicline 0.5 mg OD x 3 days then varenicline 0.5mg BID x 4 days
  Then can consider an increase to varenicline 1mg bid x 11 weeks or maintain varenicline 0.5mg BID (e.g., the lower dose may be appropriate if patient intolerant to higher doses or when Creatinine Clearance < 30ml/min)

The prescription may be renewed for an additional 12 weeks as required for patients who would benefit.

Desired Outcomes:

Patients ready to quit or reduce smoking will be provided with the appropriate pharmacologic smoking cessation aids and counseling to support them in achieving their goal.

Recipient Patients:

- Patient in preparation/action stage of readiness to quit or reduce smoking
- Patient willing and able to follow up with health care providers on a regular basis as per the smoking cessation plan

Authorized Implementer(s):

Regulated Health Professional (s) working within the smoking cessation program/clinic/ or service according to their scope of practice including:

- Completion of a recognized smoking cessation training program (e.g., Centre for Addiction and Mental Health (CAMH TEACH Program), Ottawa Model for Smoking Cessation Education and Training, and/or interprofessional core competencies for smoking cessation
- Review of the Medical Directive and any additional training on an annual basis
- Review of the varenicline product monograph
- Demonstration of understanding of varenicline, criteria, and protocols affiliated with its usage

Indications:

All patients under the care of a primary care provider who are seen for a smoking cessation consult (*Quit Plan Visit*) and for whom varenicline is deemed appropriate for their smoking cessation plan.

Contraindications

Absolute Contraindications:

- Under 18 years of age
- Previous adverse drug reaction to varenicline
- Presently taking varenicline (CHAMPIX)
- Pregnancy or breast feeding
- Creatinine Clearance < 30ml/min AND taking cimetidine, ranitidine or famotidine

Relative Contraindications:

- Combination therapy with Nicotine Replacement Therapy (NRT)

- Recent history of nausea and vomiting
- Creatinine Clearance < 30ml/min
- History of mental health illness
- History of seizures
- History of alcohol use

Patient Consent: Consent is implied when the patient has participated in shared decision-making prior to initiation, adjustment, renewal, or discontinuation of varenicline.

Guidelines for Implementing the Directive:

During initial consultation:

- Authorized Implementer(s) assess the patient's health history, including smoking history

For subsequent visits:

- Authorized Implementer(s) assess smoking status, withdrawal symptoms, cravings, & any side effects or adverse events
- Monitor renal function for patients with history of renal failure.

A change in dose or discontinuation of varenicline may be necessary if patient is still smoking, experiences any side effects or adverse events.

The Authorized Implementer(s) will advise patient taking varenicline to:

- Not engage in potentially hazardous tasks, such as driving a car or operating heavy or dangerous machines, until patient knows how varenicline may affect them
- Avoid alcohol while taking varenicline
- Register for the Smoking Cessation Follow-up Support Program/Service or have a follow-up visit within the recommended timeframe from the initial prescription as per the smoking cessation plan
- Set a quit date (varenicline should be started 1-2 weeks before the quit date)
- Report to the Authorized Implementer(s) or primary care provider if continuing to smoke while taking varenicline after 2 weeks post initiation
- Seek medical attention for any 'serious' side effects or adverse events
- Report any possible side effects to the prescribing health professional or their primary care provider

Documentation & Communication:

The Authorized Implementer(s) will document that the contraindication screening was completed and the varenicline therapy initiated, renewed, titrated, and/or discontinued.

Documentation should also include:

- Date and time
- Assessment in determining need to implement this directive
- Evaluation of the patient's response to treatment (e.g., reported side effects)
- Varenicline name, dose, route, frequency, and duration
- Refills
- Authorized Implementer's name, designation, and signature
- Medical Directive Title & Number

Communication should include:

- The prescription for varenicline will be provided to the patient with a copy in the chart
- Notify patient's primary care provider when initiating, renewing, titrating and/or discontinuing varenicline as per the patient's smoking cessation plan
- If patient is still smoking, experiences any side effects or adverse events
    - This will be communicated to the prescribing health care professional and primary care provider and documented in the chart
    - The primary care provider will be notified of any serious adverse events within the

recommended timeframe as per the smoking cessation plan

- Authorized Implementer(s) carrying out this directive may direct questions to the primary care provider at any time
- Authorized Implementer(s) will seek consultation with the primary care provider regarding individual patient issues/care as needed

Review and Quality Monitoring Guidelines:

- The Medical Director/Lead Physician, is responsible to review and modify the directive on an annual basis, as required
- If new information becomes available between annual reviews, such as new clinical best practice recommendations, the directive will be reviewed by an Authorizer and an Implementer
- The Authorized Implementer(s) is responsible to monitor the use of this Medical Directive and to review its use on an annual basis & communicate to the Medical Director/Lead Physician/ Nurse Practitioner

Administrative Approvals (as applicable):

Appendix B Attached: **Yes** X **No** **Title:** Authorizer Approval Form

Approving Physician (s) or Nurse Practitioners Authorizer (s):

The Medical Director/Lead Physician will also sign the signature page at the back of the directive, authorizing use of the directive.

Adapted from:

University of Ottawa Heart Institute. (2011). The Prescription of Varenicline/CHAMPIX-Primary Care Medical Directive. Health Promotion & Disease Prevention Program: Ottawa Model for Smoking Cessation in Primary Care.

Pfzier Canada Inc. (2015). CHAMPIX Product Monograph.

Appendix A

Varenicline Dosing Instructions

Following one week of titration, there is a choice of two doses for varenicline: 0.5 mg BID or 1.0 mg BID.

As shown in the table below, the two titration schedules are identical from Day 1 to Day 7, separating at

Day	**Dosing regimen** **0.5 mg BID**	**1.0 mg BID**
Days 1 – 3:	0.5 mg once daily	0.5 mg once daily
Days 4 – 7:	0.5 mg twice daily	0.5 mg twice daily
Day 8 – onward	0.5 mg twice daily	1.0 mg twice daily

Day 8 when the patient either remains on 0.5 mg BID or moves up to 1.0 mg BID.

- The choice of dosing regimen should be based on the prescribing health professional's judgment and patient preference, following discussion with the patient.
- Once varenicline treatment is initiated, the dose may be changed, temporarily or permanently, according to patient and prescribing health professional judgments on tolerability and efficacy. The use of varenicline 0.5 mg BID is an appropriate option for those who are unable to control nausea or other side effects in other ways.
- Patients should be treated with varenicline for 12 weeks. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment with varenicline may be considered to facilitate the maintenance of abstinence.
- Patients should return to clinic within 3 weeks of initiating varenicline for a follow-up assessment.

The use of other smoking medication therapies in combination, or the use of doses appropriate to the smoking history/circumstances of the patient may be appropriate in certain situations.

Appendix B

Authorizer Approval Form

Name	Signature	Date

Last Updated September 14, 2017