



MEDICAL DIRECTIVE

SMOKING CESSATION – VARENICLINE (NYFHT-006C)

DEFINITION

The NYFHT Smoking Cessation Program provides support to smokers who are actively seeking assistance with smoking cessation. In addition to providing information and support to these patients, the program will also provide an assessment of appropriateness for use of smoking cessation aids, including the facilitation of active treatment.

Varenicline (Champix®) increases the likelihood of success relative to no treatment or NRT and has a similar likelihood of success to bupropion (Zyban®).

PHYSICIAN'S ORDERS

- Order and renew varenicline (Champix®) for smoking cessation according to dosing protocol for up to a 12 week treatment course (Appendix 1)

PERSONS AUTHORIZED TO CARRY OUT THIS DIRECTIVE

- Clinical Pharmacist working in the NYFHT (minimum standards required to carry out directive include registration with Ontario College of Pharmacists' [RPh] and Doctor of Pharmacy degree [PharmD], or at the discretion of the Medical Director)
- Nurse Practitioner working in the NYFHT

SITUATIONAL CIRCUMSTANCES REQUIRED

- Adult patients (\geq 18 years old)
- Current tobacco smoker
- Referral to "Smoking Cessation Program" by physician (written or verbal)
- Absence of specific contraindication to varenicline (Champix®) (Appendix 2)

RISKS AND PREDICTABLE OUTCOMES

Risk

- Medication related adverse effects (Appendix 3)

Predictable Outcome

- Improved success with smoking cessation
- Improved patient satisfaction and disease awareness
- Improved patient access to care

CONTRAINDICATIONS TO THE IMPLEMENTATION OF THE DIRECTIVE

- Specific contraindication to varenicline (Champix®) (Appendix 2)

SCHEDULE FOR REVIEW OF MEDICAL DIRECTIVE

- Every 2 years (minimum) or at the discretion of the members of the NYFHT

REFERENCES

CPS

MEDICAL DIRECTIVE DEVELOPMENT

Dr. K. Wintemute, Medical Director

Dr. J. Hunchuck, Pharmacist

C. Lang, Nurse Practitioner

DATE

March 28, 2011

APPENDIX 1 – VARENICLINE DOSING PROTOCOL

Day of Therapy	Dose
1 – 3	0.5 mg daily
4 – 7	0.5 mg BID
8 – End of Treatment	1 mg BID (0.5 mg BID alternative)

APPENDIX 2 – CONTRAINDICATIONS TO VARENICLINE

The only absolute contraindications to varenicline (Champix®) is hypersensitivity to the agent, including angioedema, and history of severe dermatologic reaction to the agent, including Stevens-Johnson syndrome (SJS) and erythema multiforme (EM). However, based on reports from Health Canada indicating a risk of neuropsychiatric adverse events (depressed mood, agitation, aggression, hostility, changes in behavior, suicide related events, and worsening of pre-existing psychiatric disorders), patients with psychiatric disorders or current treatment with the following medications will be declared to have a contraindication to varenicline (Champix®) for the purposes of this medical directive and initiation of varenicline (Champix®) will only be after consultation with the physician.

- SSRI (fluoxetine, paroxetine, citalopram, sertraline)
- SNRI (venlafaxine, duloxetine)
- DA (olanzapine, risperidone, quetiapine, haloperidol)

Additionally, there is limited experience with the use of varenicline (Champix®) in pregnancy, and as such it will be declared a contraindication for the purposes of this medical directive.

APPENDIX 3 – ADVERSE EFFECTS OF VARENICLINE

Common	<ul style="list-style-type: none">• GI (nausea, flatulence, dyspepsia, constipation, increased/ decreased appetite)• CNS (insomnia, abnormal dreams, headache)• Dermatologic (rash)
Rare	<ul style="list-style-type: none">• Dermatologic (SJS, EM)• Angioedema• Neuropsychiatric (depressed mood, agitation, aggression, hostility, changes in behavior, suicide related events, and worsening of pre-existing psychiatric disorders)

