

## **CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION**

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### **VARENICLINE TARTRATE (Champix™ – Pfizer Canada Inc.)**

#### **Description:**

Varenicline is a partial agonist of the  $\alpha 4\beta 2$  nicotinic receptor subtype. It is approved for smoking-cessation treatment in adults in conjunction with smoking-cessation counselling.

#### **Dosage Forms:**

0.5 and 1 mg tablets. The recommended dose is 0.5 mg once daily for days one to three, 0.5 mg twice daily for days four to seven and 1 mg twice daily from day eight to the end of the 12 week course of treatment.

#### **Recommendation:**

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that varenicline be listed for adults who have failed to quit smoking on their own and desire pharmacologic assistance. Treatment should be limited to a 12 week treatment course and combined with an intensive smoking-cessation counselling program.

#### **Reasons for the Recommendation:**

1. Varenicline, in conjunction with smoking-cessation counselling, has been shown to result in higher rates of abstinence from smoking when compared with smoking-cessation counselling alone or bupropion plus smoking-cessation counselling.
2. Based on an economic evaluation submitted by the manufacturer which compared the effect of varenicline for smoking-cessation treatment to other treatment strategies over an individual's lifetime, varenicline appears to be more effective and cost saving.

#### **Summary of Committee Considerations:**

The Committee considered a systematic review of randomized controlled trials (RCTs) of at least six months duration in adult cigarette smokers. Eight placebo-controlled RCTs in a total of 5,873 participants met the inclusion criteria for the systematic review and three of these trials also included a comparator arm of bupropion. The proportion of varenicline treated participants that achieved continuous abstinence from smoking at 52 weeks ranged from 17% to 36% and all trials reported statistically significant improvements in favour of varenicline. A pooled analysis of six placebo controlled RCTs showed that the number need to treat (NNT) with varenicline to achieve one additional non-smoker at 52 weeks was seven when compared to placebo and 14 when compared to bupropion.

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### **Common Drug Review**

The RCTs did not report any difference in the incidence of serious adverse events between varenicline, bupropion or placebo. In the pooled analysis, varenicline treated participants were less likely to discontinue treatment compared to those treated with bupropion. The most commonly observed adverse events associated with varenicline are nausea, abnormal dreams, constipation, flatulence, and vomiting.

Varenicline costs \$283 for a 12 week course of treatment, compared to \$144 for a 12 week course of bupropion (Zyban<sup>®</sup>) and \$225 to \$283 for a 12 week course of nicotine replacement therapy administered by patch. An economic evaluation submitted by the manufacturer reported that varenicline was associated with lower costs and greater health gains compared to bupropion and nicotine replacement therapies. While this evaluation was based on a number of assumptions, the Committee felt that varenicline was cost-effective given its demonstrated efficacy and the cost difference compared to other treatments.

**Of Note:**

1. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.
2. The RCTs of varenicline excluded patients with significant cardiovascular, respiratory and psychiatric illness, yet these are groups in which smoking-cessation therapies are commonly used.

**Background:**

CEDAC provides formulary listing recommendations to publicly funded drug plans. Recommendations are based on an evidence-based review of the medication's effectiveness and safety and an assessment of its cost-effectiveness in comparison to other available treatment options. For example, if a new medication is more expensive than other treatments, the Committee considers whether any advantages of the new medication justify the higher price. If the recommendation is not to list a drug, the Committee has concerns regarding the balance between benefit and harm for the medication, and/or concerns about whether the medication provides good value for public drug plans.