Unrestricted public coverage is needed for smoking cessation pharmacotherapies

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■ Cite as: *CMAJ* 2024 January 22;196:E53-5. doi: 10.1503/cmaj.231333

In 2010, an editorial in *CMAJ* advocated that governments pay for smoking cessation medications.[1] Thirteen years later, major gaps in coverage for these effective and inexpensive medications continue to exist, including within provincial drug benefit programs. Tobacco use is a leading cause of preventable death in Canada,[2] and it is time for governments to ensure that all people with provincial drug benefits have access to smoking cessation medications.

Pharmacotherapies are effective for smoking cessation. In a phase-4 randomized controlled trial, people treated with varenicline for 12 weeks had cessation rates of 22% at 24 weeks compared with 9% among those receiving placebo.[3] Meta-analyses have found that combination nicotine replacement therapy (NRT), which combines the nicotine patch with a short-acting nicotine formulation, has similar cessation rates to varenicline.[4] Cytisine is a smoking cessation pharmacotherapy with similar effect sizes to varenicline.[5] Bupropion has smaller effect sizes than varenicline but is superior to placebo in helping people stop smoking.[3,4]

Provincial drug benefit plans, which generally provide coverage for people receiving social assistance or who meet age- or income-based thresholds, restrict coverage for these medications.[6] Coverage for NRT and cytisine is limited, in part, because they are regulated by Health Canada as natural health products. The Ontario Drug Benefit program, for example, generally does not provide coverage for natural health products. Ontario residents can obtain 8–26 weeks of NRT if they enroll in the Smoking Treatment for Ontario Patients program (https://www.nicotinedependenceclinic.com/en/stop/home). However, requiring enrolment in a separate program creates barriers for patients hoping to start or continue NRT, including after discharges from inpatient units and emergency departments, or after visits with non-enrolled clinicians. In British Columbia, people can receive a maximum of 12 weeks of NRT coverage through public drug benefits, but only if they do not receive other smoking cessation pharmacotherapies during the year. In Alberta, people are restricted to a $500 lifetime NRT limit. Cytisine is not covered through any of these programs.

Key points

- Pharmacotherapies for smoking cessation, such as varenicline, bupropion, nicotine replacement therapy and cytisine improve smoking cessation rates.
- Despite the low costs and clinically important benefits of these medications, provincial drug benefit plans restrict coverage for these drugs.
- Provincial governments should remove restrictions on smoking cessation pharmacotherapy coverage within provincial drug benefit plans.

Varenicline, a partial agonist at the $\alpha_4\beta_2$ nicotinic receptor, has annual time restrictions for public drug coverage ranging from 12 weeks in Ontario and British Columbia to 24 weeks in Quebec and Alberta. These time limits reflect prescription lengths in placebo-controlled trials and a study comparing 24 weeks of varenicline to 12 weeks, which found that extended prescriptions conferred no additional benefit among people ready to quit.[7] However, other studies have found benefit from longer prescriptions for people with severe mental illness and those who wish to gradually quit. Among people with schizophrenia and bipolar disorder who stopped smoking with varenicline, those randomly assigned to receive varenicline maintenance therapy were more likely to be not smoking at 1 year than people randomly assigned to no maintenance.[8] Among people willing to quit within 12 weeks by gradually reducing their cigarette consumption, a 24-week course of varenicline increased cessation rates compared to placebo.[9,10] This gradual quit approach is 1 of 3 recommended dosing strategies with varenicline in the Health Canada–approved product monograph, yet people receiving public drug benefits in Ontario or British Columbia would exhaust their varenicline coverage halfway through a 24-week course.[9] Bupropion, when prescribed for smoking cessation, has similar restrictions in provincial drug formularies as varenicline.[6]

Restrictions on smoking cessation coverage in public drug benefit programs do not reflect the relapsing–remitting nature of

tobacco use disorder. People often try to stop smoking many times, sometimes more than once a year, before they are able to stop smoking.[11] Varenicline remains efficacious among people with previous varenicline use.[9] Limiting people to 12 weeks of 1 of NRT, varenicline or bupropion per year, as BC does, prevents sequential treatment if the first medication is not effective, and time limits in other jurisdictions prevent repeat treatment episodes.

These limits result in the differential treatment of people with tobacco use disorder compared with those with other chronic diseases. Medications for most chronic diseases have unlimited coverage in the public drug formularies, with no restrictions on the number of treatment trials per year. People with mental illness and substance use disorders have high rates of smoking and high tobacco-related mortality; restrictions on access to smoking cessation medications disproportionately affect them.[12]

With their low costs and clinically important benefit, smoking cessation pharmacotherapies are cost effective.[13] Approximately 10% of health care costs in Ontario are estimated to be attributable to smoking.[14] The costs of smoking cessation interventions are low compared with the costs of treating cancer, chronic obstructive pulmonary disease and other chronic diseases that are associated with smoking. For example, through the Ontario Drug Benefit program, generic varenicline costs $1.85 per day, and NRT purchased through retail pharmacies costs as little as $3 per patch and $0.28 per piece of gum. A propensity-score weighted cohort study conducted among nearly 590 000 people in the US Veterans Affairs system who screened positive for tobacco use in 2011 found that incremental cost-effectiveness ratios of smoking cessation pharmacotherapies were US$4705 per quit (pooled across all pharmacotherapies).[15] Other studies found that people who stop smoking gain, on average, approximately 2 years of life, suggesting costs per life-year gained of approximately US$2350.[15] This is lower than the incremental cost-effectiveness ratio of many other medical interventions.[15]

The inequitable coverage of smoking cessation pharmacotherapies can and should be addressed. Ideally, provincial governments would provide universal coverage for smoking cessation pharmacotherapies. Short of this, provinces should remove time limits for varenicline and bupropion reimbursement and reimburse prescribed NRT and cytisine without annual or lifetime limits.

Removing restrictions on smoking cessation medications in provincial drug benefit programs would bring several benefits. These changes would make it financially feasible for covered patients to obtain the optimal smoking cessation medication for their circumstances. Patients would be supported through multiple attempts at smoking cessation. It would be easier for people to use medications with a goal of smoking reduction instead of abstinence. Finally, these changes would reduce the structural stigma against people with tobacco use disorder that is reinforced by current restrictions in the public drug formularies.

Campaigns to reduce smoking rates over the past 50 years have been an important public health success. However, access to evidence-based medications remains unnecessarily restricted for people covered by provincial drug plans. Closing this coverage gap is a necessary step to ensure that everyone who wants to stop smoking has access to the tools to do so.

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Competing interests: Robert Kleinman reports receiving research funding through the Centre for Addiction and Mental Health Discovery Fund and research funding and training support through the Research in Addiction Medicine Scholars Program (R25DAO33211, National Institute on Drug Abuse) for work outside of this project, as well as a travel award from the American Psychiatric Association for work outside of this project. Peter Selby reports receipt of funding from the Canadian Institutes of Health Research, Canadian Cancer Society, Pfizer Inc., Pfizer Canada, Ontario Lung Association, Health Canada, Medical Psychiatry Alliance, Ontario Ministry of Health and Long-term Care (MOHLTC), Public Health Agency of Canada, Juvenile Diabetes Research Foundation and Brain Canada Foundation. Dr. Selby has

received honoraria for speaking engagements from the Canadian Partnership Against Cancer, Toronto Public Health, Ontario Association of Public Health Dentistry and ECHO. Dr. Selby was a member of the scientific advisory committee of the Canadian Centre on Substance Use and Addiction and a member of the RCP Smoking Cessation Advisory Committee of Cancer Care Ontario, and is an advisory board member of the Chronic Pain and Opioid Stewardship Project of ECHO Ontario, MOHLTC. He is a member of the Smoking Cessation Advisory Committee for Ontario Health–Cancer Care. Peter Selby also reports that through an open-tender process, Johnson & Johnson, Novartis and Pfizer Inc. are vendors of record for having provided smoking cessation pharmacotherapy for research studies at free or discounted rates. No other competing interests were declared.

This article has been peer reviewed.

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Contributors: Robert Kleinman conceived the project and drafted the manuscript. Both authors revised it critically for important intellectual content, gave final approval of the version to be published and agreed to be accountable for all aspects of the work.

Funding: Peter Selby holds the Vice-Chair, Research and Giblon Professor in Family Medicine Research, a university named professorship at the University of Toronto. He is also a funded senior scientist at the Centre for Addiction and Mental Health.

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