2019

Nicotine Replacement Therapy: The Case & Roadmap for Comprehensive Private Coverage

PDCI | MARKET ACCESS

CONTENTS

1. Executive Summary 2
2. Background & Objective 2
3. The Case for Employer-Sponsored Access to NRT 3
   3.1. Smoking Has Significant Impacts On the Employer's Bottom Line 4
   Premature Death 5
   Absenteeism: Sick Days and DIsability Claims 5
   Productivity 5
   Drug Plan Costs 5
   Employee Satisfaction & Retention 6
   Smoking Accommodation & Legislation 6
   3.2. NRT Plays an Integral Role in the Smoking Cessation Armamentarium 6
   3.3. Current NRT Access Options Are Insufficient for Many Canadians 7
   NRT Self-Purchase Creates Cost Barriers To Optimal Access 7
   Public Health Programs' NRT Offerings Can Be Limited 8
   Existing Employer-sponsored Smoking Cessation Programs Can Have Blind Spots 9
   3.4. Expanded Access to NRT Would Be Highly Affordable For Most Private Plans 10
4. The Roadmap for Employer-Sponsored NRT Reimbursement 11
   4.1. Pathways to Improve NRT Access 11
   Tax Status as PHSP Would Not Be Implicated by Coverage of OTC NRT 12
5. Conclusion 13
6. References 14

This research, commissioned by J&J Consumer Healthcare, was conducted and reported independently by PDCI Market Access.

1. EXECUTIVE SUMMARY

Nicotine dependence is a serious and complex addiction. Smoking is a significant, preventable cause of morbidity and premature death worldwide. The incredibly damaging effects of smoking on individual and population health are well documented; so too are its effects on public healthcare systems, the national economy, to the workplace and to employers' bottom lines.

Employees who smoke daily are estimated to cost their employers about $4,256 a year[7], up from $2,565 since 1997[6]. Employer costs are due to premature death, absenteeism and short- and long-term disability claims related to smoking-related illnesses, decreased productivity, and increased drug benefit claims, to name a few. Employers, therefore, have much to gain by supporting employees in their efforts to quit smoking.

Despite a declining trend in the Canadian smoking rate (from almost 24% of Canadians in 1999[8, 9]) an estimated 5.2 million or 16.9% of Canadians smoked daily or occasionally in 2016[9], costing their employers year over year. Reasons for the decline are complex and multi-factorial, but at least in part attributable to the implementation of numerous tobacco control policies in both the public and private sectors, and the availability of new medical technologies and psychosocial resources aimed both at preventing Canadians from taking up smoking and supporting them to manage or overcome nicotine dependence. Despite this declining trend, more can be done to further reduce the smoking rate across the country, and in turn, the impact smoking has on the health of Canadians and their employers.

Nicotine Replacement Therapy (NRT), including patches, gum, lozenges, mouth spray, and inhaler are designed to deliver nicotine in a controlled fashion, assuaging the nicotine withdrawal symptoms which often thwart quit attempts. NRT is effective – and some evidence suggests it's instrumental to – helping employees to overcome nicotine dependence by effectively combatting withdrawal symptoms.[10] However, access barriers to NRT have impeded its optimal use.

Employers have an important incentive to minimize NRT access barriers for their employees. Recent clarifications by the Canada Revenue Agency (CRA) on its position on Private Health Services Plans (PHSP) favourably clarify tax rules for reimbursing non-prescription health products and provide an opportunity for employers to reimburse over-the-counter (OTC) NRT products within extended health benefits packages offered to employees. Reimbursing NRT can occur while maintaining the employer's PHSP tax status. Together, these circumstances provide employers an important opportunity to facilitate better access to the NRT options that will assist employees' efforts to quit smoking for good.

Employers who pursue this opportunity to improve NRT access by following the roadmap outlined in this report will realize the many benefits of smoking cessation, including a healthier workforce, improved productivity and presenteeism, and reduced burden on their benefits & disability expenses now and for years to come.

2. BACKGROUND & OBJECTIVE

Smoking is a significant and preventable cause of morbidity and premature death worldwide. The Conference Board of Canada estimated that 45,464 deaths in Canada in 2012 were attributable to smoking – this represents 18.4% or nearly 1 in 5 of all deaths.[3] This is an increase from the 37,000 smoking-related deaths estimated in 2002.[11]

Morbidity associated with smoking includes numerous cancers, respiratory disease, cardiovascular disease and diabetes, eye conditions, infertility & impotence, and oral health diseases. Smoking-related illnesses and chronic diseases have significant impacts on workers' ability to attend and function optimally at work, and management of their chronic conditions are typically associated with high drug costs.

It is well documented that smoking is more than simply a bad habit. The Canadian Centre for Addiction and Mental Health classifies nicotine dependence as an addiction involving physical and psychological factors, which make it very difficult to stop using tobacco.[12] As a complex and powerful addiction, evidence demonstrates:

- combination therapy including NRT (i.e. the concurrent use of prescription medicines and NRT) is better than prescription medicines alone in combatting the breakthrough cravings[13, 14] which can foil quit attempts;
- combination use of different NRT formats (e.g. the simultaneous use of NRT gum in addition to wearing a patch) is more effective than NRT monotherapy;[15]
- treatment for this disorder, if delivered only in discrete episodes of care, yields disappointing long-term quit rates;[16]
- Canadians who successfully quit smoking require an average of 3.2 attempts before succeeding.[3, 5]

Canadians who successfully quit smoking require an average of 3.2 attempts before succeeding.[5]

Additionally, the barriers & success factors for overcoming nicotine dependence are not universal. For this reason, success requires persistent and consistent access to a wide variety of resources and treatment options. Improved access to smoking cessation resources including NRT can address the complex and multi-factorial reasons for why quitting smoking has proven so difficult for so many Canadians, despite recurrent efforts and stated desires to quit for good.

Recent research (discussions with Canadian benefits advisors and a review of workplace smoking cessation programs) highlight that access to smoking cessation resources including NRT products may be sub-optimal, and indicate that more could be done to further reduce the smoking rate in Canada and its corresponding health and economic costs.[2]

The objectives of this report are:

- To summarize literature confirming the employer and workplace benefits of smoking cessation among employees and the role of NRT reimbursement in helping employees to quit;
- To highlight the opportunity for private drug plans to reimburse NRT products while remaining compliant with the newly clarified CRA position on Private Health Services Plans (PHSP) status, and
- To provide private payers and plan sponsors with practical guidance for how they may seize this opportunity to maintain their PHSP status and corresponding tax incentives while also providing NRT reimbursement for eligible employees via their extended health plans.

3. THE CASE FOR EMPLOYER-SPONSORED ACCESS TO NRT

In Canada, federal and provincial governments have recognized the immense return on investment in designing public policies and investing in public health initiatives shown to effectively deter Canadians from smoking. These

investments are returned to these same governments and their taxpayers manifold when the health of the population is improved, and health care system costs directly linked to the management of smoking-related illnesses are avoided. The Conference Board of Canada estimated that direct health care costs of smoking to be in excess of $6.5 billion in 2012, while expenditures on tobacco control efforts amounted to $122 million.[3]

The deleterious ramifications of smoking in Canada, however, are far more than a public health problem alone. Equally significant – but often under acknowledged – are the direct and indirect effects smoking can have on the economy as a whole, and on individual employers. These effects provide employers with opportunity for a large return on investment from employer-sponsored smoking cessation programs which can fill gaps left by public health smoking cessation programs.

3.1. SMOKING HAS SIGNIFICANT IMPACTS ON THE EMPLOYER'S BOTTOM LINE

The smoking rate in Canada has declined in recent years, but working age individuals tend to have higher rates of smoking compared to those less likely to be in the workforce. The age range with the highest smoking rates for both genders is 20-34 (25.8% of males and 18.2% of females), while the lowest rate occurs in Canadians aged 12-17 (3.9% of males and 3.3% of females), and those over 65 (11% of males and 8.1% of females), making working age Canadians an important target group for smoking cessation efforts.

According to Statistics Canada, regional distribution of smokers is highest in Newfoundland (23.4%) and Saskatchewan (20.1%). Provinces with the lowest smoking rates are British Columbia (13.2%) and New Brunswick (14.2%).[17] Of note, Quebec has been able to achieve lower smoking rates, declining at a faster rate than other provinces[18], since providing widespread coverage for smoking cessation therapies via the public drug program, which has also extended access for members of private drug plans in Quebec, as legislation requires private drug plans in Quebec provide at minimum the same level of coverage as the public plan.

Employees who smoke daily are estimated to cost their employers up to $4,256 a year,[2] up from $2,565 since 1997.[6]

A Statistics Canada Survey on tobacco use confirmed more than three quarters of Canada's smokers in 2011 had actively worked in the preceding 12 months of the survey, and 19% of the working population were smokers, representing a higher percentage than was found in the non-working population.[8] Statistics Canada analytics in 2011 found industries with the highest smoking prevalence to include Construction (34%), Mining, Oil and Gas Extraction (29%), and Transportation (29%).[2] Together these numbers highlight the opportunity and incentive for employers, particularly in sectors with high smoking rates, to take steps today that can mitigate costs now and in the years to come.

A 2002 report by the Canadian Centre for Substance Use and Addiction estimated costs of tobacco use in Canada to be $17 billion, with $12.5 billion due to premature morbidity and mortality, and $4.4 billion due to direct health care costs.[11] Employees who smoke daily are estimated to cost their employers up to $4,256 a year[2], up from $2,565 since 1997[6]. A disaggregation of the significant direct and indirect cost components which create pressures on employers' bottom line are described below.

PREMATURE DEATH

Approximately 45,500 Canadians die from smoking each year, including almost 1,000 due to second-hand smoke exposure, and smoking-attributable mortality resulted in nearly 600,000 potential years of life lost in 2012.[3] The Conference Board of Canada estimated this results in $2.5 billion worth of forgone earnings resulting from smoking-attributable premature deaths in 2012.[3] With each smoking-related death of an actively working individual, lost skills, knowledge and productive capabilities take a toll on the work place. So too does productivity decline for other employees within the organization when dealing with the emotional toll of having lost a colleague.

ABSENTEEISM: SICK DAYS AND DISABILITY CLAIMS

Employees who smoke have a higher risk of developing many chronic conditions (including cancers, heart disease and diabetes) and contracting infections or other acute illnesses.[2] Morbidity caused by smoking related illnesses means smokers use more sick days on average than their non-smoking counterparts and are also more likely to require short- and long-term disability claims. Data from the Canadian Community Health Survey suggested daily smokers or those who recently quit took 2.4 more sick days in 2010 than their non-smoking colleagues.[2] Daily smokers are also three times more likely to become unable to work due to a chronic condition: 6.5% of all daily smokers and recent quitters versus 2% of their non-smoking colleagues are forced out of the labour force for at least three months due to a chronic condition.[2] About $6.9 billion of foregone earnings in 2012 were a result of long-term disability, with another $182 million in production losses associated with short-term disability.[3]

Daily smokers or those who recently quit took 2.4 more sick days in 2010 than their non-smoking colleagues…and are also three times more likely to become unable to work due to a chronic condition.[2]

PRODUCTIVITY

Since 1995, every province and territory in Canada has now implemented legislation prohibiting smoking in indoor public places, including workplaces. Employees who smoke spend a considerable amount of time outside or in other designated smoking areas on unsanctioned smoking breaks to manage their nicotine dependence. The Conference Board of Canada estimates smokers to take 40 minutes per work day in unsanctioned smoke breaks, creating a significant dent in these employees' productive capacity.[2]

DRUG PLAN COSTS

In 2012, drug expenditures related specifically to smoking related illnesses were $1.7 billion.[3]

Linked to the fact that the health state of smokers is more likely worse than non-smokers, smokers usually make use of more prescription drugs to treat and manage medical conditions secondary to smoking than non-smokers. It was estimated that in 2012, drug expenditures related specifically to smoking related illness were $1.7 billion.[3]

EMPLOYEE SATISFACTION & RETENTION

Several surveys have found that a large majority of both smokers and non-smokers favour smoke-free workplaces (smokers report appreciating restrictions on the ability to smoke as reinforcement for their own desires and efforts to cut down).[19] For example, a study of employee attitudes and behaviors in hospitals pre- and post-implementation of a smoke-free policy found the policy had a positive impact on employees' ability to do their job, their interactions with others and their overall job satisfaction. Additionally, the number of smokers reporting a desire to quit smoking doubled following implementation of the policy.[20]

SMOKING ACCOMMODATION & LEGISLATION

Unless they choose to become smoke-free, and in order to protect health and job satisfaction of non-smoking employees, often employers must invest in infrastructure to accommodate smoking, such as creating designated smoking areas within or nearby the work place. Additionally, employers must work to ensure they are complying with legislation surrounding any designated smoking areas, including that they be properly ventilated, cleaned and maintained. The City of Ottawa estimated that the capital cost for a designated smoking room would be about $3,500 per smoking employee before accounting for maintenence.[19]

Additionally, provincial and federal human rights codes prohibit employers from discriminating based on a disability, but neither the legislation nor human rights tribunals has made perfectly clear whether smoking is considered a disability. For this reason, employers may be better advised to address the smoking rate in their workforce by offering resources to quit as opposed to screening for smoking status during the hiring process and potentially facing human rights complaints.

3.2. NRT PLAYS AN INTEGRAL ROLE IN THE SMOKING CESSATION ARMAMENTARIUM

Nicotine dependence is extremely difficult to overcome. Well-validated studies have shown that smoking cessation treatments significantly increase the chances of quitting smoking and are cost-effective.[21] In particular, NRT is an effective intervention helping smokers to overcome nicotine dependence and its use has been found to double long-term success.[1] NRT also appears effective in the reduction of smoking for those who do not express a desire to quit, making its access key to going smoke free even in a population which may have low motivation.[22]

The barriers and success factors for overcoming nicotine dependence are not universal. As such, a range of treatments and programs, including those that address both the physical and psychological nature of a smoking addiction, appear to be the most successful.[3] Indeed, combination therapy including NRT has been found to be better than prescription medicines alone to combat breakthrough cravings and lead to a successful quit attempt.[13, 14] Furthermore, a recent network meta-analysis of studies in the Cochrane Database of Systematic Reviews concluded that combination use of NRT – that is, the simultaneous use of two types of NRT products such as chewing NRT gum in addition to wearing a patch – are more effective than single types of NRT. Different types of NRT were generally equally effective but combinations of NRT outperformed single formulations consistently.[15]

Put into practice, a 2015 Canadian study examining trends in use of smoking cessation products found that smokers with comprehensive coverage for more than one form of smoking cessation support were more likely to remain abstinent after a quit attempt than those with coverage for only one type of smoking cessation aid.[23]

3.3. CURRENT NRT ACCESS OPTIONS ARE INSUFFICIENT FOR MANY CANADIANS

Smoking rates in Canada have declined in recent years: from almost 24% of Canadians in 1999 to 16.9% in 2016.[8, 9] Reasons for the decline are complex and multi-factorial, but at least in part attributable to the implementation of numerous tobacco control policies and resources in both the public and private sectors, as well as access to pharmaceuticals indicated in smoking cessation. Despite this declining trend, there were still 5.2 million Canadian smokers in 2016. With about two-thirds of smokers expressing intent to quit within the next six months[24], many Canadians could benefit from additional resources to make their next quit attempt their last.

This section outlines the existing NRT access options in Canada and other resources supporting smoking cessation currently available to some or all Canadians, highlighting why they may not be sufficient to addressing nicotine dependence as the complex addition that it is.

NRT SELF-PURCHASE CREATES COST BARRIERS TO OPTIMAL ACCESS

In the 1990s, NRT prescription products were recognized as integral to smoking cessation and the public health objective to reduce smoking prevalence. In 1998, Health Canada reclassified NRT products so they would be available to Canadians on an over-the-counter (OTC) basis, with the rationale being the change would improve Canadians' NRT access since they would not need to visit a physician and be prescribed NRT if and when they decided to quit. However, while the reclassification eliminated one access barrier, it caused a different, affordability one: Canadians whose drug benefits plans did not cover OTC products were left to self-purchase NRT.

Because smoking in Canada has persistently been linked to inequalities in socioeconomic status[25, 26], the policy change unintentionally created an important NRT access gap which persists today: following the OTC switch, Canadians with less disposable income faced more barriers to quit than those with more disposable income. Over time after the change, socio-economically disadvantaged smokers have been found to be disproportionately affected by the harms of tobacco use.[25] Notwithstanding some limited smoking cessation programs targeting low-income individuals across the country, many Canadians of lower socioeconomic status have been left to fight their dependence with large affordability barriers and an insufficient patchwork of potential resources.

Despite its proven role to double the chances of successfully quitting, only one in five smokers use NRT as part of their cessation strategy.[1] Underutilization may be explained in part by cost barriers: in a 2012 survey, more than half of smokers identified product cost as a barrier to NRT self-purchase.[4]

For Canadians battling addiction to nicotine, self-purchase of NRT comes with important and challenging trade offs. When an individual under the physiological, mental and social stresses of nicotine withdrawal is forced to persistently choose between purchase of cigarettes or purchase of NRT – even if the NRT is more affordable on a cost per day basis - it becomes clear to understand why it is easy for smokers to relapse, preferring to buy the pleasure of cigarettes versus the less gratifying NRT option that would help them quit in the long run. Additionally, the choice between tobacco and NRT self-purchase becomes particularly complicated given that NRT use is often first combined with a reduce-to-quit strategy – meaning the individual does not simply replace the cost of cigarettes with the cost of NRT, but rather must buy both products until they can use only NRT – and the fact that low personal income is strongly associated with a higher prevalence of smoking[3], makes many smokers more likely to experience financial constraints and consequences more seriously than would individuals with higher personal income.

Despite its proven role to double the chances of successfully quitting, only one in five smokers use NRT as part of their cessation strategy.[1] Underutilization may be explained in part by cost barriers: In a 2012 survey, more than half of smokers identified product cost as a barrier to NRT self-purchase.[4] The Canadian Agency for Drugs & Technologies in Health (CADTH) has similarly recognized that cost can be a barrier for Canadians to access these medications.[27]

Some provinces (Manitoba and British Columbia) have exempted NRT products as goods subject to provincial sales taxes, meanwhile taxes on cigarettes remain high. Together this influences the cost equation surrounding NRT self-purchase for individuals trying to quit.

In its September 2017 report, the Ontario Tobacco Research Unit (OTRU) recognized the conflict between the ease of access to NRT versus the difficulty of choosing to quit tobacco use. OTRU noted "full coverage interventions significantly increased the proportion of smokers who attempted to quit." Despite the ability of an individual to self-purchase NRT, OTRU goes on to recognize that "health insurance coverage for smoking cessation is important as evidence shows that it promotes uptake and reduces smoking rates."[28] [29]

PUBLIC HEALTH PROGRAMS' NRT OFFERINGS CAN BE LIMITED

As explained earlier, research has shown that successful smoking cessation requires comprehensive, persistent and consistent access to a wide variety of resources and treatment options. Government sponsored public health programs, such as Ontario's Smoking Treatment for Ontario Patients (STOP) Program, British Columbia's Smoking Cessation Program, Alberta's QuitCore, and the Quebec Public Prescription Drug Insurance Program, provide many Canadians with access NRT and have likely been instrumental in the successful quit attempts of countless Canadians. However, supplies and eligibility under these programs can be limited, creating barriers for some who may require additional quit attempts, or who must experiment with different combinations of strategies before successfully becoming smoke-free.

The BC Smoking Cessation Program, for example, allows only for a single quit attempt each calendar year, providing a 12-week supply of ***either*** NRT ***or*** prescription smoking cessation drugs at 100% of the cost. Since 2005, the Ontario STOP program has similarly offered smoking cessation medicines including NRT free of charge to participants for a course of 12 weeks per year. The Alberta QuitCore program offers enrolled participants up to $500 of NRT coverage per lifetime and additional coverage for prescription smoking cessation medications if prescribed. The Quebec Public Prescription Drug Insurance Program provides for free prescription medicines and NRT for up to 12 weeks per year.[30, 31] Where NRT is covered by the Quebec public drug plan and legislation in the province requires that private plans cover – at a minimum – all products listed on the public formulary, most Quebec-based employees have some access to NRT, though this access is often no more than what is available via the public program.

Nonetheless, smoking rates are lower in provinces with more robust public access to NRT. For example, BC which reimburses NRT products through its Pharmacare Program had the lowest smoking rate in 2015 (10.2%) followed by Ontario (11.3%), potentially indicating a relationship between access to smoking cessation resources and successful quit attempts.

While the patchwork of public health resources as available offer a start for many Canadians, they often fall short of addressing nicotine dependence as the complex, chronic relapsing condition that it is. Because research suggests a strong link between successful quitting and duration of use, as well as the need for multiple quit attempts, it is here

where employer-sponsored private drug plans can play a key role in supplementing patients to have longer, sustained access to these important treatments.

EXISTING EMPLOYER-SPONSORED SMOKING CESSATION PROGRAMS CAN HAVE BLIND SPOTS

Many employers already invest in strategies to support smoking cessation among their employees. However, a review cataloguing the existing employer-sponsored smoking cessation programs in Canada, found that the offerings could be much more comprehensive.[32]

Evidence is clear that a range of treatments and programs, including those that address both the physical and psychological nature of a smoking addiction, appear to be the most successful. According to Statistics Canada, Canadians who successfully quit smoking required an average of 3.2 attempts before succeeding.[3] For these reasons programs need to be both comprehensive in options and duration of treatment supported to mitigate any access barriers. It is therefore recommended that barriers to sustained and repeated quit attempts be removed to allow for more than one quit attempt per year.

Many private drug plans in Ontario began offering smoking cessation benefits as an option for employers under an increasing demand for wellness initiatives following the 2006 implementation of the Smoke-Free Ontario Act. However, as an OTC product, NRT tended to be excluded.[33] Additionally, a 2017 survey reported that many employers offered some form of smoking cessation treatments to their employees, but the level of coverage varied and was often restrictive with regards to the variety of products accessible, and/or duration of use sponsored, which could undermine employees' efforts to quit.[29]

- While 73% of plans provide coverage for prescription smoking medicines, only 25-40% cover NRT patches, gums, lozenges, mouth sprays or inhalers[1,30]
    - Of the 73% of plans with coverage for prescription medicines, approximately 16% have annual and 48% have lifetime maximums on the amounts which can be claimed;
    - Of those plans covering NRT products, an estimated 31% are estimated to have annual maximums and 38% to have lifetime maximums on amounts reimbursed.[32]
    - Annual and lifetime maximums can impede the access cycle for many individuals, inadvertently stifling quit attempts.

Overall, private plans offering prescription drug therapy without NRT are missing an important piece of the smoking cessation puzzle. So too are those continuing to use annual and lifetime maximums based on the evidence and costs as assessed when NRT first came to market in the 1990s. Enhancing benefit programs to include NRT comprehensively will offer smokers optimal access to the combination of therapies shown to more likely lead to success. Reda et al. examined the effectiveness of insurance coverage for smoking cessation in a 2012 systematic review and meta-analysis.[34] Results found that insurance coverage including both pharmacologic and behavioral support significantly increased the proportion of smokers who attempted to quit, who used smoking cessation treatments and who maintained smoking cessation after 6 months compared to those who had no coverage.

[1] Informed by direct discussions with payer representatives.

Therefore, reducing out of pocket costs for effective treatments such as NRTs can be effective to increase both the number of people who try to quit and the number of those who are successful.[34]

Benefits of smoking cessation begin immediately for both the employee and employer. But like many common, complex chronic diseases, curing nicotine dependence requires that patients find the right treatment options for them that address all the complex, multifactorial causes of their continued smoking. The only way they can do this is if employers treat smoking cessation options the same way they do other drugs and treatments for complex, multifactorial conditions (e.g. depression, epilepsy), by ensuring their employees have consistent and comprehensive access to the proven solutions to help them quit.

3.4. EXPANDED ACCESS TO NRT WOULD BE HIGHLY AFFORDABLE FOR MOST PRIVATE PLANS

Despite decreased smoking rates in Canada over the last 20 years, nicotine dependence continues for a cohort of Canadians. For employers who recognize the role they can play to limit their exposure to the negative effects of smoking on the workforce, there's much good news:

Annual NRT expenditures by the Quebec public drug program have been steady: between $6-7 million since 2010. In 2017 the program provided NRT products to almost 30,000 Quebec residents for a drug cost of $7 million – representing a mere 0.2% of the drug plan's $3 billion drug costs that year.

1. A significant amount of public resources devoted to the matter of quitting smoking has decreased the total number of smokers in Canada since NRT was first introduced to the Canadian market. Statistics Canada reports that in 2016 about one quarter of Canadians (24.7%) were former daily or occasional smokers[9], meaning their quit attempts have been successful and persistent.
2. Smokers' motivation to quit smoking as measured by their expressed desires is at an all time high due to recent significant public health education efforts and public policies designed to incentivize Canadians towards quitting.

Therefore, potential costs to an employer-sponsored drug plan to supplement existing public programs and resources with regards to NRT reimbursement is likely to be small and predictable based on the beneficiary population at hand.

Considering NRT expenditures by the Quebec public drug program, for example, annual costs have been steady between $6-7 million since 2010. In 2017 the program provided NRT products to almost 30,000 Quebec residents for a drug cost of $7 million – representing a mere 0.2% of the drug plan's $3 billion drug costs in 2017.[2]

According to a survey of existing employer-sponsored smoking cessation programs, total program costs are typically quite affordable, averaging $6,265 per year and ranging from and average

Cost of combination NRT treatment per successful quit is estimated to be $2,377 – about half of the annual cost to an employer in terms of lost productivity per smoker.

[2] Source: PDCI C-MAP™ Drug Claims Database.

of $2,375 for employers with fewer than 500 employees to $10,367 for organizations with more than 1,500 employees.[32]

Additionally, the cost of combination NRT treatment per successful quit is estimated to be $2,377 – which is about half of the annual cost to an employer in terms of lost productivity per smoker. This is the estimated cost of combination NRT assuming use of one Nicoderm® Patch ($3.91 per patch) and 15 pieces of Nicorette® Gum ($5.52 for 15 pieces) per day for a daily total of $9.43[4], and assuming that to successfully quit an individual will need to undergo an average of 3.2 quit attempts each comprising a 12-week course of therapy.[5]

4. THE ROADMAP FOR EMPLOYER-SPONSORED NRT REIMBURSEMENT

Given the case made above supporting the benefits to employers and the role they can play to facilitate NRT reimbursement, as well as the substantial evidence for both comprehensive and consistent access to a wide variety of smoking cessation options, this section provides a roadmap on how payers and plan sponsors can help close the gaps in NRT coverage for their beneficiaries.

4.1. PATHWAYS TO IMPROVE NRT ACCESS

Private health plan sponsors have several avenues open to them to facilitate broader, more effective access to NRT products and thereby realize the benefits of a healthier workforce. To get started:

1. **Review drug plan contract language** to identify whether historically implemented annual or lifetime maximums on NRT use creates unintended access barriers to these proven treatments. In many cases, NRT products were added to private drug plans when they first entered the market in the 1990s. Evidence on the effectiveness of NRT has since matured and the costs associated with reimbursement of NRT today are relatively small compared to what they may have been at that time. For these reasons, a review of NRT coverage status and criteria is recommended.
2. **Lift Annual & Lifetime Limits.** Employees continuing to smoke may have tried and failed several times to quit. After reaching life-time maximums these employees may no longer seek to quit due to the absence of plan coverage.
3. **Take advantage of recent CRA guidance concerning Private Health Services Plans (PHSPs).** If your drug plan does not reimburse NRT, consider its addition as potentially the most straightforward approach to facilitating access. If there are concerns about potential tax consequences of reimbursing a product which is not eligible for the Medical Expense Tax Credit (METC), read more about the recent CRA position on PHSPs the box below. CRA provided this guidance to ease concerns among employers about their PHSP design and remaining compliant with tax rules. The 10% clarification provides plan sponsors with flexibility to offer plans that meet the needs of their employees without risking their PHSP status, if the plan design accepts and reimburses pre-defined non-prescription or otherwise METC-ineligible products.
4. **Consider NRT as a reimbursable category for plans with health spending accounts.** For those private plans with health spending accounts or lifestyle spending accounts, offering NRT through one of these programs may offer a path to confidently contain benefit costs, while continuing to support comprehensive access to NRT. Include NRT in the list of eligible products to ensure patients have access to an optimal care plan that can include combination treatment if necessary. Offering unrestricted access will not increase plan costs significantly and will allow employees to customize the resources necessary to help the quit for good.

TAX STATUS AS PHSP WOULD NOT BE IMPLICATED BY COVERAGE OF OTC NRT

According to recent payer research, one reason extended health care plans have not provided coverage of OTC NRT products is the perception among plan sponsors that by doing so, their beneficial tax standing as a Private Health Services Plan (PHSP) could be at risk.

Canadian employers enjoy tax benefits from establishing CRA-recognized PHSPs. These plans allow employers to deduct their portion paid for benefit plan premiums as a business expense for tax purposes. Prior to 2015, providing coverage for *any* drug products ineligible for the METC could put a PHSP at risk. As an OTC drug product, NRT products are ineligible for METC.

However, recent CRA guidance confirms that private benefits plans **can** provide access for employees seeking NRT to help them quit smoking, paving the way for plan sponsors to harvest the clear benefits associated with a smoke-free workforce. The recent CRA guidance clarifies that private drug plans can maintain their tax status while reimbursing non-METC eligible products, provided these expenses are less than 10% of total plan costs.

Prior to 2015, in order for a PHSP to maintain its status, all – that is, 100% - of its medical expenses were required to be for METC-eligible items. Since then, however CRA clarified that "substantially all" of its premiums paid must be for METC-eligible products. CRA further clarified that "substantially all" means at least 90%; essentially providing flexibility for plan sponsors to design plans which reimburse non-METC-eligible products that it finds to be of value for its benefits plans, up to 10% of the plan's total expenditures. Based on the demographic data and trends in smoking cessation, as well as the case study of Quebec's public drug plan costs (in 2017 NRT costs represented 0.2% of its $3 billion drug expenditures), it is very unlikely that reimbursement of NRT expenses could approach 10% of a PHSP's total expenditures.

5. **Implement a Smoking Cessation or Wellness Program.** Plan sponsors have much to gain by helping employees break down barriers in access to NRT as part of their wellness programs. Additionally, employees appreciate when employers demonstrate a commitment to employee health by providing comprehensive, integrated health programming which is innovative and forward thinking in helping them to be healthier.
6. **Support a smoke-free culture.** More and more workplaces are becoming smoke-free environments. Hospital grounds, university campuses and numerous other workplaces are realizing the benefits of a culture which promotes healthier living. As employees see their employers taking an active interest in their health, private drug plans will be called upon more to support the smoke-free environment. As an added bonus to having happier non-smokers, a study published in the American Journal of Public Health reported that more than 26% of employees who smoked were able to successfully quit when smoking was prohibited in their workplace, compared with a 19% quit rate in a workplace that did not have a policy restricting smoking.[35]

5. CONCLUSION

Employers have much to gain by supporting employees in their efforts to quit smoking. By ensuring comprehensive and consistent coverage of NRT products, employers can effectively complement and fill gaps remaining in existing public and private sector resources devoted to smoking cessation, helping their employees to overcome NRT affordability barriers. Pursuing a more comprehensive NRT access strategy would not only allow employers to harvest important savings from having a healthier workforce, they would incur only minor costs in doing this, and would not risk their status as a PHSP. Indeed, there has never been a more perfect time to reconsider and enhance NRT's place in employer-sponsored extended health plans.

6. REFERENCES

1. Cummings KM, Hyland A. Impact of nicotine replacement therapy on smoking behavior. Annu Rev Public Health. 2005;26:583-99. doi: 10.1146/annurev.publhealth.26.021304.144501.

2. Bounajm F, Stonebridge C, Thériault L. Briefing 3: Benefits of Workplace Programs. Ottawa, Canada: The Conference Board of Canada, October 2013.

3. Dobrescu A, Bhandari A, Sutherland G, Dinh T. The Costs of Tobacco Use in Canada, 2012. Ottawa, Canada: The Conference Board of Canada, October 2017.

4. McNeil Consumer Healthcare. HelpThemQuit.ca [Internet]. [updated June 18, 2018; cited August 11, 2018]. Available from: https://www.helpthemquit.ca/treatment/costs-coverage.

5. Canadian Tobacco Use Monitoring Survey: Quitting Smoking. Health Canada, January-December 2003.

6. The Conference Board of Canada. Smoking and the Bottom Line: Updating the Costs of Smoking in the Workplace. Ottawa, Canada: August 2006.

7. Benefits of Workplace Programs. Ottawa, Canada: The Conference Board of Canada, October 2013.

8. Statistics Canada. Canadian Tobacco Use Monitoring Survey: overview of historical data, 1999 to 2012. [updated 2013-10-01; cited August 11, 2018]. Available from: https://www.canada.ca/en/health-canada/services/publications/healthy-living/overview-historical-data-1999-2012.html.

9. Statistics Canada. Health Fact Sheet: Smoking, 2016. September 27, 2017.

10. Stead LF, Perera R, Bullen C, et al. Nicotine replacement therapy for smoking cessation. Cochrane Database Syst Rev. 2012;11:CD000146. doi: 10.1002/14651858.CD000146.pub4.

11. Rehm J, Baliunas D, Brochu S, et al. The Costs of Substance Abuse in Canada 2002. Ottawa, Canada: Canadian Centre on Substance Abuse, March 2006.

12. Nicotine dependence [Internet]. Centre for Addiction and Mental Health; 2018. [cited August 11, 2018]. Available from: https://www.camh.ca/en/health-info/mental-illness-and-addiction-index/nicotine-dependence.

13. Shah SD, Wilken LA, Winkler SR, Lin SJ. Systematic review and meta-analysis of combination therapy for smoking cessation. J Am Pharm Assoc (2003). 2008;48(5):659-65. doi: 10.1331/JAPhA.2008.07063.

14. Chang PH, Chiang CH, Ho WC, Wu PZ, Tsai JS, Guo FR. Combination therapy of varenicline with nicotine replacement therapy is better than varenicline alone: a systematic review and meta-analysis of randomized controlled trials. BMC Public Health. 2015;15:689. doi: 10.1186/s12889-015-2055-0.

15. Cahill K, Stevens S, Perera R, Lancaster T. Pharmacological interventions for smoking cessation: an overview and network meta-analysis. Cochrane Database Syst Rev. 2013(5):CD009329. doi: 10.1002/14651858.CD009329.pub2.

16. Joseph AM, Fu SS, Lindgren B, et al. Chronic disease management for tobacco dependence: a randomized, controlled trial. Arch Intern Med. 2011;171(21):1894-900. doi: 10.1001/archinternmed.2011.500.

17. Statistics Canada. Table 13-10-0096-10 Smokers, by age group 2018.

18. Propel Centre for Population Health Impact University of Waterloo [Internet]. Waterloo, ON. Tabacco Use in Canada, Smoking in the Provinces: Quebec [cited September 1, 2018]. Available from: https://uwaterloo.ca/tobacco-use-canada/adult-tobacco-use/smoking-provinces/quebec.

19. Health Canada. Towards a Healthier Workplace: A guidebook on Tobacco Control Policies. Ottawa, Canada. 2007. Available from: https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/hc-ps/alt_formats/hecs-sesc/pdf/pubs/tobac-tabac/work-trav/travailler-eng.pdf.

20. Unrod M, Oliver JA, Heckman BW, Simmons VN, Brandon TH. Outdoor smoking ban at a cancer center: attitudes and smoking behavior among employees and patients. J Public Health Manag Pract. 2012;18(5):E24-31. doi: 10.1097/PHH.0b013e31822d4bb5.

21. Ekpu VU, Brown AK. The Economic Impact of Smoking and of Reducing Smoking Prevalence: Review of Evidence. Tob Use Insights. 2015;8:1-35. doi: 10.4137/TUI.S15628.

22. Canadian Agency for Drugs and Technologies in Health (CADTH). Nicotine Replacement Therapy for Smoking Cessation or Reduction: A Review of the Clinical Evidence. Rapid Response Report. January 16, 2014.

23. White CM RV, Reid JL, Ahmed R. Stop-smoking medication use, subsidization policies, and cessation in Canada. American Journal of Preventive Medicine. 2015;49(2):188-98.

24. Reid JL, Hammond D, Rynard VL, Burkhalter R. Tobacco Use in Canada: Patterns and Trends, 2015 Edition. Waterloo, ON: Propel Centre for Population Health Impact, University of Waterloo. Available from: https://uwaterloo.ca/tobacco-use-canada/sites/ca.tobacco-use-canada/files/uploads/files/tobaccouseincanada_2015_accessible_final-s.pdf.

25. Reid JL, Hammond D, Driezen P. Socio-economic Status and Smoking in Canada, 1999-2006: Has There Been Any Progress on Disparities in Tobacco Use? Can J Public Health 101(1):73-8.

26. Corsi DJ, Lear SA, Chow CK, Subramanian SV, Boyle MH, Teo KK. Socioeconomic and Geographic Patterning of Smoking Behaviour in Canada: A Cross-Sectional Multilevel Analysis. PLOS ONE. 2013;8(2). Epub 2013 Feb 28.

27. Canadian Agency for Drugs and Technologies in Health (CADTH). In Brief A Summary of the Evidence: Drugs for Smoking Cessation. Ottawa, Canada: May 2016.

28. Zhang B, Schwartz R. Health Insurance Coverage and Smoking Cessation The Ontario Tobacco Research Unit, September 2017.

29. Schwartz R, Haji F, Babayan A, Longo C, Ferrence R. Public Health Policy in Support of Insurance Coverage for Smoking Cessation Treatments. Healthc Policy. 2017;12(4):56-68.

30. McDonald J, Coady K, Saltman D. The postal code lottery of cancer prevention in Canada: Discrepancies in Public and Private Funding for Smoking Cessation Products. Cancer Advocacy: Report Card on Cancer in Canada 2012-13, 2013.

31. Canadian Partnership Against Cancer. Cessation Aids and Coverage in Canada. [updated April 2018]. Available from: https://content.cancerview.ca/download/cv/prevention_and_screening/tobacco_cessation/documents/smoking_cessation_coverage_infographic_enpdf?attachment=0.

32. Lamontagne E, Stonebridge C. Briefing 2: Smoking Cessation Programs in Canadian Workplaces. Ottawa, Canada: The Conference Board of Canada, June 2013.

33. Jackson M, Gaspic-Pickovic M, Cimino S. Description of a Canadian employer-sponsored smoking cessation program utilizing community pharmacy-based cognitive services. Canadian Pharmacists Journal. 2008;141(4):234-40.

34. Reda AA, Kotz D, Evers SM, van Schayck CP. Healthcare financing systems for increasing the use of tobacco dependence treatment. Cochrane Database Syst Rev. 2012(6):CD004305. doi: 10.1002/14651858.CD004305.pub4.

35. Moskowitz JM, Lin Z, Hudes ES. The impact of workplace smoking ordinances in California on smoking cessation. Am J Public Health. 2000;90(5):757-61.