DRUG BENEFIT COMMITTEE (DBC) DRUG REVIEW SUMMARY:
Champix (varenicline tartrate) # 1650

DRAFT as of 2007 September 6	**Date Reviewed by the DBC**
	October 25, 2007

Issues for Consideration
▪ CDR recommends listing varenicline (Champix) for smoking-cessation in 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 counseling program. ▪ Currently, Pharmaceutical Services Division (PSD) does not reimburse smoking-cessation products. ▪ A comperator product bupropion is reimbursed as a Limited Coverage benefit in the treatment of depression only.
Brand Name:
Champix
Generic Name:
Varenicline tartrate
Manufacturer:
Pfizer Canada Inc.
Indication per Manufacturer's Submission:
Smoking-cessation treatment in adults in conjunction with smoking-cessation counseling.
Manufacturer's Listing Request:
Manufacturer is requesting that varenicline be considered for reimbursement by BC PharmaCare based on its clinical evidence and cost-effectiveness.

Dosage Forms:
0.5 mg tablet 1 mg tablet
Notice of Compliance (NOC):
January 24, 2007
Release Date:
April 11, 2007
Patent Date:
Champix has three registered patents expiring on the following dates: November 13, 2018 April 26, 2022 November 4, 2022

DRUG BENEFIT COMMITTEE (DBC) DRUG REVIEW SUMMARY:
Champix (varenicline tartrate) # 1650

CEDAC Recommendation, Date and Rationale:

On August 16, 2007, CEDAC recommended 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 counseling program.

Reasons for the Recommendation:

1. Varenicline, in conjunction with smoking-cessation counseling, has been shown to result in higher rates of abstinence from smoking when compared with smoking-cessation counseling alone or bupropion plus smoking-cessation counseling.
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 favor of varenicline. A pooled analysis of six placebo controlled RCTs showed that the number needed 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.

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 patients 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) 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.

Submission Received by PharmaCare on:

May 4, 2007

Known Unapproved or Potential Indications for Use:

None

DRUG BENEFIT COMMITTEE (DBC) DRUG REVIEW SUMMARY:
Champix (varenicline tartrate) # 1650

Compassionate Release Prior to NOC?

☒ No ☐ Yes

Pricing from Manufacturer's Submission (includes 7% markup):

0.5 mg tablet $1.8030

1 mg tablet $1.8030

CDR Comparators and PharmaCare Benefit Status:

Nicotine replacement therapy (NRT) – patch, gum, inhaler – Non Benefit

Bupropion – Under review, Limited Coverage SA for treatment of depression, Non Benefit for smoking-cessation

Limited Coverage criteria:

Diagnosis indicating depression Approval period: Indefinite

Mechanism of Action:

The efficacy of varenicline in smoking-cessation is believed to be a result of varenicline's partial agonist activity at the α4β2 nicotinic acetylcholine receptor (ie agonist activity to a lesser degree than nicotine), while simultaneously preventing nicotine binding (ie antagonist activity).

In vitro, varenicline binds with higher affinity to the α4β2 receptor subtype than to other common nicotinic receptors (>500-fold α3β4; >3,500-fold α7; >20,000-fold α1βγδ), or to non-nicotinic receptors and transporters (> 2,000-fold).

Electrophysiology studies *in vitro* and neurochemical studies *in vivo* have shown that varenicline acts as a partial agonist at α4β2 nicotinic acetylcholine receptors. In the absence of nicotine, varenicline's agonist activity is at a significantly lower level than nicotine, but sufficient to activate the central nervous mesolimbic dopamine system, believed to be the neuronal mechanism underlying reinforcement and reward experienced upon smoking. In the presence of nicotine, which competes for the same human α4β2 nicotinic acetylcholine receptor (nAChR) binding site, varenicline prevented nicotine from activating the α4β2 receptor, since it has higher affinity for this site and this prevented full stimulation of the central nervous mesolimbic dopamine system.

Varenicline is also a partial agonist at α3β4 receptors, but a full agonist at α7 receptors and a full agonist at 5-HT3 receptors.

Varenicline has moderate affinity for the 5-HT3 serotonergic receptor (Ki=350 nM), at which it acts as a weak, full agonist (EC50=0.96 □M). Varenicline-induced nausea shortly after dosing, when gastrointestinal levels are predicted to be temporarily high, may be due to activation of this peripheral receptor, in addition to a possible role for peripheral α3β4 and/or central α4β2 nAChRs.

Adverse Drug Reaction Reporting from Health Canada as of September 5, 2007

None reported

Health Canada Issues:

None

DRUG BENEFIT COMMITTEE (DBC) DRUG REVIEW SUMMARY:
Champix (varenicline tartrate) # 1650

Miscellaneous Issues:
None

PROVINCIAL SUMMARY		
Date Completed:	**September 10, 2007**	
Province	**Status**	**Details**
British Columbia	UR	
Alberta	UR	
Manitoba	UR	
New Brunswick	UR	
Newfoundland & Labrador	UR	
Nova Scotia		
Ontario	UR	
Prince Edward Island	UR	
Quebec	UR	
Saskatchewan	UR	

LST – Listed as a full benefit in the formulary; **LWC** – A restricted benefit for which coverage criteria are published (e.g., exception drug status, limited use benefit, special authorization with published criteria); **LSM** – list in similar manner as other drugs in class or group; **NL** – CEDAC Recommendation that drug be not listed; **NLT** – Reviewed by drug plan and decision is not to list; **UR** – Under review; **CBC** – Not listed as a benefit but covered on a case-by-case basis – e.g., Section 8 in Ontario or Special authorization in MB; **EXC** – Excluded (belongs to category of drugs that the drug plan excludes on basis of policy or mandate – e.g., fertility agents); **APA** – Covered by another program or agency (e.g., Cancer Boards, HIV/AIDS program); **NS** – No Submission received.

Manufacturer's BIA:

Based on the manufacturer's budget impact analysis (BIA), the following is the financial impact of listing varenicline as PharmaCare benefit:

s.17

DRUG BENEFIT COMMITTEE (DBC) DRUG REVIEW SUMMARY:
Champix (varenicline tartrate) # 1650

COMPARATIVE DAILY COST OF THERAPY (includes 7% markup)				
Drug Name	**PharmaCare Status**	**Cost/Unit**	**Dose Range**	**Treatment Cost of Therapy (12 weeks)**
Varenicline (Champix) 0.5 mg tablet	Under review	$1.8030	**Day 1-3**: 0.5mg daily **Day 4-7:** 0.5mg bid **Day 8-end of treatment:** 1mg bid	$297.4950
Varenicline (Champix) 1 mg tablet	Under review	$1.8030		

Not Responsive

BC PHARMACARE DRUG EXPENDITURE APRIL 1, 2006 TO MARCH 31, 2007

Chemical	mg	# Patients	Total Claimed per Day*	Total Claimed*	Total Paid by PSD*
Not Responsive					
TOTAL					

* bupropion is a limited coverage drug for depression indication only.

TOTAL BC DRUG EXPENDITURE JANUARY 1, 2007 TO AUGUST 31, 2007

Chemical	# Patients	Total Claimed per Day	Total Claimed
Varenicline (Champix) 0.5 mg tablet			

Varenicline (Champix) 1 mg tablet
Not Responsive

Drug Submission rec'd: 2007/05/04
IS rec'd: 2007/05/09 (10:20AM)

Drug Base Update Request Form requiring Drug Under Review, Non- Benefit Drug, LCA Change *or* Other Change to PharmaNet Drug Base Information

Request Date: 2007/05/04	***Effective Date: 2007/05/11 JH***	***Authorized by: tf***
Drug Information: **Brand Name**: Champix		***Manufacturer**: Pfizer Canada Inc.* **Chemical / Generic Name*: varenicline tartrate***

DIN	*Strength*	*Form*
2291177	*0.5 mg*	*tablet*
~~*22991185*~~	*1mg*	*tablet*
2291185		

Therapeutic class of drug/s: 920000881 – 0.5mg; and 920000882 – 1 mg

[X] ***Drug Under Review*** **- enter 'UR' in Benefit Group Section and Therapeutic Class**
- file in Folder 4 – UR Action

[ ] ***Non-Benefit Drug*** **- enter Therapeutic Class only**
- file in Folder 3 – Manufacturer Letter Action

[ ] ***LCA Change*** **- enter information as directed in Special Instructions**
- file in Folder 6 – IS Support Newsletter Action

[ ] ***PharmaNet Information Change***
- unless otherwise indicated, file in Finals for Filing

***Special Instructions*:**
HIBC: Please add as "Under Review"

Din 22991185 has been corrected to 2291185 on the form. JH

Drug Submission rec'd: 2007/05/04
IS rec'd: 2007/09/25 (2:32pm)

Drug Base Update Request Form requiring Drug Under Review, Non- Benefit Drug, LCA Change *or* Other Change to PharmaNet Drug Base Information

Request Date: 2007/09/25	***Effective Date: 2007/09/29***	***Authorized by: tf***
Drug Information:	***Manufacturer****: Pfizer*	
Brand Name: Champix Starter pack	**Chemical / Generic Name*****: varenicline tartrate***	

DIN	*Strength*	*Form*
2298309	*0.5mg and 1 mg*	*tablet*

Identify a Drug in the same Therapeutic Class: Please create a new thera class 920000

[X] ***Drug Under Review*** - **enter 'UR' in Benefit Group Section and Therapeutic Class**
- file in Folder 4 – UR Action

[ ] ***Non-Benefit Drug*** - **enter Therapeutic Class only**
- file in Folder 3 – Manufacturer Letter Action

[ ] ***LCA Change*** **- enter information as directed in Special Instructions**
- file in Folder 6 – IS Support Newsletter Action

[ ] ***PharmaNet Information Change***
- unless otherwise indicated, file in Finals for Filing

Special Instructions**: HIBC: Please add as under review. Done WP**
New Thera class is 920000910.

INTRODUCTION

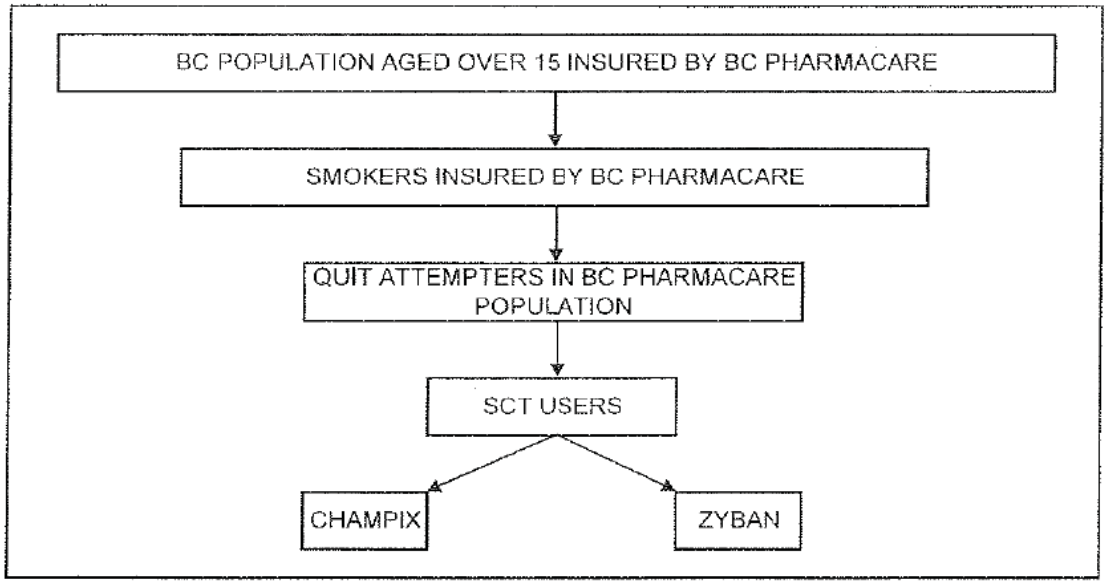
Promoting smoking cessation is a critical priority to improve British Columbians health outcomes and the sustainability of British Columbia's healthcare system. However, smoking cessation treatments (SCT) are currently not reimbursed by the British Columbia's PharmaCare Program (PharmaCare). In August 2007, the Common Drug Review issued a positive recommendation to list varenicline (Champix). Improving access to SCTs with proven efficacy may be one of the most effective strategies to decrease the smoking prevalence in BC and to improve the population's health in the long-term.

OBJECTIVE

The objective of this budget impact analysis (BIA) was to estimate the financial impact associated with the reimbursement of two SCTs with proven efficacy, Champix and Zyban, by PharmaCare.

METHODS

To evaluate the financial impact of listing Champix and Zyban on the BC Pharmacare formulary, the following patient flow model was used to evaluate the projected number of Champix and Zyban users in a given year.



To estimate the population of smokers and quit attempters within BC Pharmacare, the *Tobacco Attitudes and Behaviours Survey Report*[1] from BC Stats was used. Based on the report's findings, it is assumed that there are currently 550,000 smokers in the BC Pharmacare population, of which 133,925 are *assumed* to reach their deductible at some point in the year, thus becoming eligible for subsidization of an eventual quit

[1] http://www.bcstats.gov.bc.ca/data/ssa/reports/tobacco/tabs2008.pdf

attempt made with a SCT method. According to BC Stats, less than half (48.5%) of these 133,925 smokers will make at least one quit attempt in a given year. Among the projected 64,954 quit attempters eligible for SCT subsidization by BC Pharmacare, 26.4% (or 17,151 smokers) are expected to use a SCT as their quit method of choice. This estimate is based on RAMQ (Quebec) data on SCT utilization. This is probably the best proxy for this analysis as the RAMQ is the only Canadian provincial drug plan to provide comprehensive SCT coverage as of today and has done so since 2000. Using Rx shares data, of the 17,151 SCT users, 15,919 are expected to be Champix users (92.8% of SCT users) and 1,231 are expected to be Zyban users (7.2% of SCT users). Finally, to project the SCT expenditures, the annual number of Champix and Zyban users was multiplied by the expected average drug cost per user as derived in the following table:

	Cost per Pills/Patches [A]	Average Treatment Duration per User (days)	# of Pills/Patches [B]	Drug Cost [C]= [A]x[B]	Wholesale Markup [D]= 7%*[C]	Inventory Allowance [E]=$0*[F]	# of Disp. [F]	Disp. Fee [G]	Disp. Cost [H]= [F]*$8.60	Total Treatment Cost [I]= [C]+[D]+[E]+[H]	Co-payment [J]=30%*[I]	Total Cost to BC Pharmacare [K]=[I]-[J]
Champix	s.17											
Zyban												

Sources
Private Sector Adherence Data - May 2009

To estimate the pool of remaining smokers at Years 2 and 3, it was assumed that 16.4% of current smokers would successfully quit every year and that 6.6% of former smokers would relapse every year, making them smokers again.

RESULTS

In the base-case scenario, the projected SCT expenditures incurred by BC PharmaCare were estimated to be s.17 in Year 1, s.17 in Year 2, and s.17 in Year 3. As such, the overall impact of reimbursing SCTs is estimated to result in total incremental drug expenditures of s.17 over the next 3 years. This estimate do not take into account the potential cost offsets resulting from a reduction in cigarette smoking-related health problems, including the provision of various medication to treat these conditions. The following table shows the budget impact for the first three years of listing both SCTs:

Budget Impact Anticipated with the Listing of Champix and Zyban by BC Pharmacare

Drug	Year 1	Year 2	Year 3	Total
Champix	s.17			
Zyban				
Total				

CONCLUSIONS

Smokers who are motivated to quit deserve support and the tools to be successful. Considering all the health and economic benefits associated with smoking cessation, the immediate incremental budget impact of SCT reimbursement to BC PharmaCare should be viewed in the context of increased savings to the BC healthcare system in the long-term and be perceived as a highly cost-effective use of BC PharmaCare's resources.

CADTH HTA Report: Pharmacologic-based Strategies for Smoking Cessation: Clinical and Cost-Effectiveness Analyses.

HTA Report Objective: This review compares the clinical effectiveness and cost-effectiveness of pharmacologic agents, with or without behavioural support programs, for smoking cessation.

Pfizer Canada- British Columbia Context Note

The CADTH HTA Report answers many questions and offers key conclusions for governments to consider, as they move forward with a SCT policy to advance healthy living and save other components of their health care systems. Many of the questions in the report are relevant to the BC environment and should be considered. In particular, the CADTH Report conclusions suggest that varenicline would be the most effective and, a value-based solution for the BC Government to consider. Further, with cost as a barrier, the report indicates that including public coverage for pharmacotherapy had even greater success than offering free NRTs.

QUESTION 1: Among the general population of (relatively healthy) smokers, what is the comparative clinical effectiveness of varenicline, bupropion, and nicotine replacement therapy (NRT)?

CADTH Report Highlights	Pfizer's Comments
• NRT (patch, gum, lozenge, inhaler, spray, and sublingual), bupropion, and varenicline were all efficacious as aids in smoking cessation when compared with placebo. • Varenicline was found to be superior to conventional nicotine patch used after quit date and bupropion. • Comparisons of the relative efficacy of bupropion and NRT or of the various forms of NRT were mostly inconclusive. • At one year, varenicline was found to be superior to bupropion (OR 1.43, 95% CrI 1.08 to 1.89) and conventional NRT used after quit date (OR 1.47, 95% CrI 1.13 to 1.93), particularly to nicotine gum (OR 1.63, 95% CrI 1.11 to 2.38) and nicotine patch (OR 1.54, 95% CrI 1.15 to 2.06).	s.21

QUESTION 2: Among the general population of smokers using varenicline or bupropion or NRT, what is the clinical effectiveness of adding a behavioural support program to drug therapy?	
CADTH Report Highlights	**Pfizer's Comments**
• The evidence showed that adding behavioural support to nicotine patch, nicotine gum, or bupropion did not have any strong impact on the overall abstinence rates of the drugs. • Types of behavioural support used varied between trials, and included advice and education sessions, helplines and telephone counselling, physician- or nurse-provided counselling, cognitive or behavioural relapse-prevention therapy, psychological treatment, and self-help prevention.	s.21
QUESTION 3: What is the impact of "free" or "paid for" pharmacotherapy on the clinical effectiveness of drugs used for smoking cessation therapy?	
CADTH Report Highlights	**Pfizer's Comments**
• Financial reimbursement and financial incentives had a positive impact on the pharmacotherapy. • The efficacy of free distribution of nicotine patches was no better than that of nicotine patch bought over-the-counter. •	s.21

s.21

QUESTION 4: Among smokers, what is the clinical effectiveness of treating specific populations (adolescents, pregnant women, and those with underlying diseases) with varenicline or bupropion or NRT, including a combination of these agents, with behavioural support programs?

CADTH Report Highlights	Pfizer's Comments
• **Adolescents, pregnant women, low-income, cancer, and post-traumatic stress disorder smokers**: varenicline data was not identified • **Substance abuse and mental disorders**: varenicline data was not identified. It is unclear if NRT (gum, patch) or bupropion is efficacious for smoking cessation in smokers with a history of depression. • **Cardiovascular or smoking-related diseases, COPD, and hospitalized patients**: NRT, bupropion or varenicline could be used as an aid for smoking cessation in smokers with cardiovascular diseases or COPD. Intensive behavioural support with follow-up contact after patient discharge from the hospital seems to be more important than pharmacotherapy in smoking cessation treatment. • Overall, the consistency of failure of short-term treatments (when active medication was stopped, the relapse rates increased) suggests that long-term therapy may be needed in some specific populations of smokers.	s.21

QUESTION 5: Among the general population of smokers, what is the cost-effectiveness of varenicline compared with that of bupropion and that of NRT?

CADTH Report Highlights	Pfizer's Comments
• Regardless of age and gender, bupropion and varenicline were dominating therapies (i.e., cost less and generate more benefit) over nicotine gum, patch, lozenge, and inhaler. • Probabilistic analyses showed that, if a drug plan's threshold to pay for an additional quality-adjusted life year (QALY) is at least $4,000 to $10,000 (depending on age and gender), varenicline would be the most cost-effective	s.21

option.

s.21

QUESTION 6: Among the general population of smokers using varenicline or bupropion or NRT, what is the cost-effectiveness of adding a behavioural support program to drug therapy?

CADTH Report Highlights	Pfizer's Comments
• The cost-effectiveness analysis of adding behavioural intervention to drug therapy was limited to the analysis of nicotine patch therapy with telephone counselling sessions. • Adding telephone counselling (four sessions, 10 to 15 minutes each) to nicotine patch therapy was not a cost-effective alternative compared with nicotine patch therapy alone.	s.21

QUESTION 7: What is the impact of co-payment (of insurance claim) or payment (i.e., purchase drug as over-the-counter product) on the cost-effectiveness of drugs used for smoking cessation therapy?

CADTH Report Highlights	Pfizer's Comments
• The analysis was limited to comparing full reimbursement of bupropion and NRT (gum, patch, and inhaler) with no reimbursement of these drugs. • If the drug plan's threshold to pay for an additional QALY is at least $900, then full reimbursement is a more cost-effective option than not reimbursing for these drugs.	s.21

	s.21

QUESTION 8: Among smokers, what is the cost-effectiveness of treating specific patient populations with varenicline or bupropion or NRT, including a combination of these agents with behavioural support programs?

CADTH Report Highlights	Pfizer's Comments
• The authors focused our cost-effectiveness analysis on two specific populations (those with cardiovascular or other smoking-related diseases — including chronic bronchitis, emphysema, asthma, vascular and pulmonary diseases, cancer, hypertension, diabetes, hyperlipidemia — and hospitalized patients) with two drug classes (NRT — gum, patch and/or inhaler — and bupropion) and no intervention. • Varenicline's cost-effectiveness in these populations was not studied.	s.21

QUESTION 9: What is the budget impact to the publicly funded drug programs of adopting the strategies that were identified as having optimal cost-effectiveness in the responses to questions 5, 6, 7, and 8?

CADTH Report Highlights	Pfizer's Comments
• Please refer to the Executive Summary for more details.	s.21

QUESTION 10: What is the budget impact to the publicly funded drug programs of implementing a payment or co-payment program for the strategies that were identified as having optimal cost-effectiveness in the responses to questions 5, 6, 7, and 8?

CADTH Report Highlights	Pfizer's Comments
• Our economic analyses concluded that providing full reimbursement was a cost-effective alternative compared with the no reimbursement option. • Therefore, the potential budgetary impact would be the same as that shown in Question 9.	s.21

QUESTION 11: What is the willingness of smokers to pay for having access to strategies identified as having optimal cost-effectiveness in the responses to questions 5, 6, 7, and 8?

CADTH Report Highlights	Pfizer's Comments
• Cost is a barrier to accessing smoking cessation medication when a coverage plan does not exist in certain jurisdictions. • Evidence showed that the provision of free drugs, reimbursement programs, and full insurance coverage increased the enrolment and had an impact on the use and the success rates. • It is increasingly likely that contemporary smokers are from lower socio-economic groups, for whom pharmacotherapy may pose absolute cost challenge in the ability to pay.	s.21

QUESTION 12: What are the general relevant planning issues related to equitable access and accountability surrounding the implementation of the treatment strategies that were identified as having, but not limited to, optimal cost-effectiveness?

CADTH Report Highlights
• Government agencies, health care programs, services, and practitioners should be held accountable for quality, safety, and cost-effectiveness of smoking cessation treatment. • An offer of assistance with smoking cessation and the delivery of smoking cessation treatment should be seen as the standard of care expected of any health practitioner who encounters smoker-patients. • There is a need for a national training and accreditation program, which would make the treatment of tobacco use and dependence accountable and standardized across all jurisdictions.

- Most Canadian hospitals have no means of identifying admitted smokers, and do not provide systematic assistance to such patients with cessation.
- Program services need to establish a performance framework with clear organizational and managerial accountability.
- Patients should expect that tobacco use will be addressed as part of their routine health care.
- Smokers from specific populations often encounter barriers and inequalities in smoking cessation treatment.
- For older adults, issues include the inaccessibility to smoking cessation aids, the misconceptions of health care providers, and the potential side effects of pharmacotherapy.
- Smoking cessation therapy in patients with co-occurring mental health or substance use disorders has been considered as low priority, and some health care professionals are reluctant to recommend smoking cessation treatment based on the belief that it could harm patients' mental health.
- Smokers of low social economic status have encountered barriers to using existing services including fear of being judged, fear of failure, low awareness of services, and misconceptions about their availability and effectiveness.
- Homeless smokers are faced with barriers including the social acceptance of tobacco use, high levels of stress, and smoking in combination with substance use.
- Many factors that contribute to the low success rate among aboriginal people include low social economic status, cultural beliefs, lack of prioritization of tobacco as a health issue, and lack of aboriginal involvement in delivery of health care services.
- The increasing availability of contraband tobacco "sabotages" the likelihood of cessation, particularly in low socioeconomic groups, because it lowers the cost of smoking, and removes the economic "advantage" of cessation products.
- There is a need, as part of a comprehensive approach to the elimination of contraband tobacco, for increasing surveillance at the borders to make it more difficult to obtain smuggled cigarettes.
- Effective intervention for younger smokers requires further research and development, because "adult-validated" treatments may be inapplicable to a young population.

QUESTION 13: What is the current public reimbursement status of pharmacologic agents for smoking cessation?

CADTH Report Highlights

- Alberta, Quebec, and the First Nations and Inuit have limited coverage for nicotine gum, nicotine patches, and bupropion.
- Varenicline is covered as limited use in Quebec, Yukon, and for the First Nations and the Inuit.

s.13, s.21

Selected publications

These publications contain information related to Pfizer products, not included in the locally approved Summary of Product Characteristics (labeling). These publications are being provided in response to an unsolicited request and are supported by the relevant scientific data, including safety data, and are meant to be non-promotional

Government of British Columbia
Continued Leadership in Tobacco Control and Cessation

Experts and Stakeholders Validate CHAMPIX (varenicline) for British Columbia

✓	CADTH HTA Report (Sept. 2010)	*"All pharmacotherapies reviewed are effective in helping the general population quit smoking, with varenicline being superior to bupropion and conventional use of nicotine patch." "Full coverage of pharmacotherapy may increase the uptake of cessation therapies and have an impact on use and success rates"*
✓	CMAJ Editorial (August 2010)	*"As an immediate first step, all provincial drug formularies should begin reimbursing evidence-based smoking cessation therapies."*
✓	Cochrane review (Reda et al. 2009)	*"The provision of SCT coverage appears to lead to: higher abstinence rates from smoking, a higher proportion of smokers making a quit attempt and more smokers using a SCT during a quit attempt"*
✓	CDR Recommendation (August 2007)	*"Champix leads to higher rates of abstinence from smoking when compared to placebo and bupropion. Over an individual's lifetime, is more effective and less costly"*
✓	BC Public Service Coverage of Champix (2007)	*"Our government has made it a goal to be a leader in healthy living and, as an employer, we are leading by example by encouraging employees to take steps to stop smoking."*
✓	Clean Air Coalition of BC – Report (Sept 2010)	*"That PharmaCare provide coverage, subject to PharmaCare Plan rules for varenicline (Champix) and buproprion (Zyban) to assist patients to quit smoking."*
✓	Provincial Health Officer - Investing in Prevention Report (Sept. 2010)	*"Each year, tobacco use kills over 6,000 British Columbians and costs the BC economy approximately $2.3 billion. Cigarette smoking is the primary risk factor for diseases of the circulatory system, cancers and respiratory diseases. Passive smoke kills up to 140 people in BC each year."*
✓	BC Health Living Alliance Report (October 2010)	*"Businesses, government and the NGO sector should work together to develop comprehensive policies on tobacco use in the workplace. This policy should also include smoking cessation resources for employees such as public and private health insurance coverage for nicotine replacement therapies (NRTs) and cessation medications."*

2

From: Chong, Elaine HLTH:EX
To: Lun, Eric HLTH:EX; Fazlagic, Tijana HLTH:EX; Chan, Dennis HLTH:EX
Cc: Galbraith, Susan HLTH:EX; Weston, Megan D HLTH:EX; Kwok, Jess HLTH:EX; Capelli, John HLTH:EX
Subject: FW: limited use
Date: July-27-11 12:23:30 PM

FYI.

My colleagues in Ontario tell me that varenicline and bupropion will be limited use benefits as of Aug 4 (LU is Ontario's version of SA though not enforced) – limited at 12 weeks. Their criteria also tie these drugs to counselling, though it is not clear how this will be enforced.

NRTs will not be listed.

EC

From:
Sent: Wed, July 27, 2011 11:56 AM
To:
Subject: limited use

Hi there,

FYI - Champix and Zyban are limited use #423 - 12 week supply per 365 days per patient for smoking cessation along with smoking cessation counseling

http://www.health.gov.on.ca/english/providers/program/drugs/formulary/41_update_z_20110726.pdf

MINISTRY OF HEALTH SERVICES
DECISION BRIEFING NOTE

Cliff # 897549

PREPARED FOR: Eric Lun, Executive Director **- FOR DECISION**

TITLE: Drug Review Listing Decision for varenicline (Champix®), bupropion (Zyban®), and Nicotine Replacement Therapy (Nicorette®, Nicoderm®, Habitrol® and Thrive™) for Smoking Cessation

PURPOSE: To make a drug review listing decision for varenicline (Champix®), bupropion (Zyban®), and Nicotine Replacement Therapy (Nicorette®, Nicoderm®, Habitrol® and Thrive™) for smoking cessation.

BACKGROUND:

- On May 9, 2011, Premier Clarke announced that nicotine replacement therapies (NRT's) will be available to all smokers in BC at no cost, and prescription drugs (varenciline and buproprion) will be covered under the PharmaCare program effective September 30, 2011.
- Varenicline (Champix®), manufactured by Pfizer Canada, and Nicoderm and Nicorette products, manufacturered by McNeil, were submitted to the Ministry of Health (the Ministry) for potential coverage for smoking cessation therapy.
- On August 16, 2007, CEDAC recommended that varenicline be listed for adults who have failed to quit smoking on their own and desire pharmacologic assistance.
- In September, 2010, the Canadian Agency for Drugs and Technologies in Health (CADTH) released final Pharmacologic-based strategies for smoking cessation Technology Report recommendations. Based on the report, varenicline was found to be superior and more cost-effective than conventional NRT's and bupropion.
- In April, 2011, the Drug Benefit Council (the Council) recommended that varenicline and bupropion be listed on the PharmaCare formulary for one 12 week course of therapy per annum (see Appendix 1 for complete recommendation).

DISCUSSION:

- The Council reviewed a systematic review of 155 reports describing 143 studies comparing the efficacy of NRT, bupropion, varenicline, or a combination thereof versus placebo. The outcome measures of the studies included continuous abstinence rates (6 months and 1 year), prolonged abstinence rates, and point-prevalence abstinence.
- Studies demonstrated that NRT, bupropion, and varenicline are all superior to placebo in terms of continuous abstinence rates at 6 months and 1 year. At 1 year, varenicline was found to be more efficacious than bupropion and NRT. No differences were observed when bupropion was compared to NRT.
- The CADTH technology report found that bupropion and NRT doubles the odds of a smoker quitting successfully and varenicline nearly triples the odds of quitting smoking.
- All treatment options, except the NRT inhaler, were associated with more adverse events than placebo; including headache, dizziness, nausea, and vomiting. NRT inhalers were associated with similar adverse effects to placebo.
- There are number of safety concerns regarding varenicline, including a Health Canada advisory regarding neuropsychiatric adverse events, and recent reports regarding

cardiovascular events. However, after considering all safety information, the Ministry concluded that the benefits of varenicline outweigh patient risk.

- At the listed prices, varenicline and bupropion were more cost-effective than NRT.
- The Business Management, Supplier Relations and Systems group has been involved in discussions with the manufacturer of varenicline (Champix®), bupropion (Zyban®), and NRTs. Drug listings are subject to product listing agreements.
- A tender was reached regarding NRT, whereby Nicoderm and Nicorette were part of the tender, but Habitrol® patches and Thrive™ gum offered the best financial options.

FINANCIAL IMPLICATIONS:

s.17

OPTIONS:

Option 1: Do not list varenicline (Champix®), bupropion (Zyban®), or NRTs (Habitrol® and Thrive™) as PharmaCare benefits.

Pro: The Ministry would avoid an incremental budget impact s.17

s.17

Con: This option limits the smoking cessation options available to residents of BC and would be inconsistent with the Premier's announcement regarding smoking cessation.

Option 2: Effective September 30, 2011, list varenicline (Champix®) and buproprion (Zyban®) as PharmaCare benefits, and list NRT (Habitrol® and Thrive™) as PharmaCare benefits under Plan S requiring no deductible as per PharmaCare coverage policies for buproprion, varenicline, and NRT. NRTs Nicorette and Nicoderm will not be added as eligible PharmaCare benefits.

Pro: Consistent with the Premier's announcement and expands treatment options

Con: The Ministry will incur estimated budget impact s.17

RECOMMENDATION: Option 2.

Original Signed By September 30, 2011

Approved Date

Eric Lun Executive Director

Drug Intelligence

Program ADM/Division:	Bob Nakagawa, Assistant Deputy Minister
Telephone:	250 952-1705
Program Contact (for content):	Tijana Fazlagic
DRILL:	Elaine Chong
Drafter:	Jillian Hardy
Date:	November 21, 2014

File Name with Path: Y:\Formulary Management - Access Restricted\FM BN's\2011\FINALS\Smoking Cessation. 897549.BN.docx

Appendix 1

Drug Benefit Council (DBC) Recommendation and Reasons for Recommendation

FINAL

Therapeutic Review of Pharmacologic-Based Strategies for Smoking Cessation

Description:

Therapeutic review of pharmacologic-based strategies for smoking cessation.

In their review, the Drug Benefit Council (DBC) considered the technology report entitled *Pharmacologic-based Strategies for Smoking Cessation* completed by the Canadian Agency for Drugs and Technologies in Health (CADTH) in September 2010, and the varenicline review completed by the Common Drug Review (CDR) in 2008. The varenicline CDR report included evidence review material and the recommendation from the Canadian Expert Drug Advisory Committee (CEDAC). The DBC also considered Clinical Practice Reviews from a general practitioner and a specialist, a review response from several product manufacturers, and feedback from patients, caregivers, patient advocacy groups, and British Columbia Health Authorities.

The following agents were included in the review:

Generic Name	Brand Name	Manufacturer
Bupropion	Zyban Wellbutrin XL Wellbutrin SR Generics SR	Valeant Canada Valeant Canada Valeant Canada Generic
Varenicline	Champix	Pfizer Canada
Nicotine Replacement Therapy (NRT)		
Various Nicotine Transdermal Patches including:	Habitrol Nicoderm Nicorette Nicotrol Prostep	Novartis Canada McNeil Canada McNeil Canada McNeil Canada Aveda Drug System Inc.
Various Nicotine Gum brands including:	Nicorette Nicotinelle Gum Thrive Gum Rugby Gum Nic-Assist	McNeil Canada Novartis Health Canada Novartis Health Canada Watson Laboratories Watson Laboratories

Generic Name	Brand Name	Manufacturer
Nicotine Lozenge brands including:	Nicorette Nicoderm Nicorette Mini Thirve Lozenges Nosmoke Lozenges	McNeil Canada Unique Pharma Inc.
Nicotine Inhaler	Nicorette Nicorol	McNeil Canada

Recommendations and Reasons for the Recommendations:

Recommendation #1: The DBC recommends listing of varenicline and bupropion for smoking cessation. The DBC recommends that one 12 week course of therapy at the manufacturer's recommended dose per annum of varenicline *or* bupropion be covered, and that the patient should be responsible for the cost of subsequent therapy.

Reasons for the Recommendation:

Clinical

- The DBC reviewed a systematic review of 155 reports describing 143 studies comparing the efficacy of NRT, bupropion, varenicline, or a combination thereof versus placebo. The outcome measures of the studies included continuous abstinence rates (6 months and 1 year), prolonged abstinence rates, and point-prevalence abstinence.
- Studies demonstrated that NRT, bupropion, and varenicline are all superior to placebo in terms of continuous abstinence rates at 6 months and 1 year. At 1 year, varenicline was found to be more efficacious than bupropion (Odds Ratio (OR) 1.43, 95% CI 1.08 to 1.89) and NRT (OR 1.47, 95% CI 1.13 to 1.94). No differences were observed when bupropion was compared to NRT.
- The CADTH technology report found that bupropion and NRT doubles the odds of a smoker quitting successfully and varenicline nearly triples the odds of quitting smoking.

Safety

- All treatment options, except the NRT inhaler, were associated with more adverse events than placebo; including headache, dizziness, nausea, and vomiting. NRT inhalers were associated with similar adverse effects to placebo.
- The DBC also considered the varenicline Health Canada advisory describing 226 Canadian cases of neuropsychiatic adverse events reported out of 708, 534 prescriptions of varenicline filled in Canada during that time period.
- DBC concluded that there did not appear to be many serious adverse events associated with these drugs, especially when combined with nicotine withdrawal.

Economic

- At the listed prices, varenicline and bupropion were more cost-effective than NRT.
- The budget impact associated with covering smoking cessation products is significant and thus preference was given to the more cost-effective agents.

Recommendation #2: The DBC recommends NRTs not be listed (with the exception of Plan G patients – See Recommendation #3). However, if NRTs were available at cost parity to bupropion/varenicline, then they should be considered as an alternative covered therapy using a similar coverage policy as bupropion and varenicline (See Recommendation #1).

Reason(s):

- There are no statistically significant differences in efficacy between bupropion and NRT pharmacotherapy, however the cost of NRTs are significantly greater than the cost of generic bupropion.
- At the listed prices, varenicline and bupropion were more cost-effective than NRT.
- Access to NRTs are available for self-medication without prescription.

Recommendation #3: The DBC does not recommend any specific population of smokers be prioritized for coverage, with the following exception: the DBC recommends that Plan G (Mental Health) patients be covered for one 12 week course of therapy per annum at the manufacturer's recommended dose of varenicline *or* bupropion *or* NRT.

Reason(s):

- The DBC concluded that mental health patients are much more likely to suffer from an addiction to cigarettes and that this cohort of patients should have access to all of the available pharmacologic options to aid in smoking cessation.
- Patients of aboriginal descent and hospitalized patients were not considered in this context as aboriginal patients receive drug coverage under the Non-Insured Health Benefits (NIHB) program, and hospital formulary committees are responsible for drug funding decisions for hospitalized patients.

Recommendation #4: The DBC recommends that behavioral support programs *not necessarily* be linked with the Ministry's smoking cessation drug coverage.

Reason(s):

- The DBC reviewed a systematic review of nine trials identified by CADTH comparing abstinence rates in patients receiving pharmacotherapy for smoking cessation alone versus pharmacotherapy plus behavioral support therapy.
- Three trials compared the nicotine patch alone versus the nicotine patch plus combination therapy, five trials compared nicotine gum alone versus nicotine gum plus behavioral therapy, and one trial compared bupropion alone versus bupropion plus behavioral therapy.
- These trials demonstrated that adding behavioral support did not have a significant impact on abstinence rates.

Recommendation #5: The DBC recommends that PSD continue to work closely with health authorities and other stakeholders to harmonize smoking cessation strategies. The DBC also recommends further review of the regular benefit drug nortriptyline for smoking cessation, as well as further research into the Ottawa model for smoking cessation.

BRITISH COLUMBIA
The Best Place on Earth

File: 70325-30/ varen
CLIFF# 897885

September 30, 2011

Mr. Christopher Smith
Manager, BC Government
Patient Access and Health Policy
Pfizer Canada Inc.
17300 Trans Canada Hwy
Kirkland QC H9J 2M5

Dear Mr. Smith:

Thank you for your submission for the inclusion of **varenicline tartrate** (**Champix®) 0.5 mg and 1.0 mg, DIN 229177, DIN 2291185, and DIN 2298309,** as eligible benefits under the BC PharmaCare program for smoking cessation.

The Ministry of Health (the Ministry) has now completed its review of this product. Effective September 30, 2011, varenicline tartrate (Champix®) will be added as an eligible Limited Coverage benefit for patients covered under Fair PharmaCare and Plans B, C, and G as part of the PharmaCare Smoking Cessation program.

Coverage of eligible smoking cessation products: varenicline, bupropion, and nicotine replacement therapy, is limited to a single 12 week (84 day) treatment course once per calendar year. Coverage is available to all smokers (and users of other tobacco products) who are BC residents and meet the general PharmaCare eligibility rules.

PharmaCare coverage is subject to the terms of the product listing agreement.

Sincerely,

Eric Lun, PharmD
Executive Director, Drug Intelligence

Drug Submission rec'd: yyyy/mm/dd
IS rec'd: September 21, 2011, 6:33:31 AM

Drug Base Update Request Form – *for Benefits*

Request Date: 2011/09/08	***Effect Date:*** **Sept 30/11 MV**	***Authorized by: jh/tf***

Drug Information:	***Manufacturer:*** Pfizer Canada
Brand Name: Champix	**Chemical / Generic Name:** varenicline

DIN	***Strength***	***Form***	***Full Drug Price***	***Full Quantity (not /unit $)***
			Manufacturer Price, no 8% markup	***Added 8% Sept 30/11 as per email***
2291177	***0.5 mg***	***tablet***	$1.7170	***1 tablet pup 1.8544***
2291185	***1 mg***	***tablet***	$1.7171	***1 tablet pup 1.8545***
2298309	***0.5mg/ 1 mg***	***tablet***	$42.93	***25 tablets pup 1.8546***

Therapeutic class of drug/s:
DIN 2291177: 920000881
DIN 2291185: 920000882
DIN 2298309: 920000911

Maximum Days Supply: 30 days

Flags:		
Trial: No	Trial Days:	Trial Plans:
Triplicate Drug: No	Generic Drug: No	RDP Drug: No
Is Din an LCA Drug: No	Current LCA Price:	
Limited Coverage Drug: No	Is DIN eligible for Special Authority? No	

Benefit Groups:
B, C , U, G

Category Designation:		
DIN in RDP Category: No	Category:	Sub-Category:
DIN in Non-RDP Category: No	Category:	Sub-Category:
Create new Non-RDP Category / Sub-Category: Yes		**9901 / 0148**

Practitioner Information:		
Practitioner Exemptions: No Assumed SA: No	Practitioner ID:	ID Ref #:
Practitioner Specialty Group: No	Group ID:	
Do other DINS exist as Special Authority's for the practitioner specialty group? No		

Note: If DIN exists as a Special Authority and a new Non-RDP Category is to be created, any existing individual DINs will require termination and re-creation under the 'new' Non-RDP Category.

Special Instructions:

HIBC: Effective September 30, 2011, please add the above three products as benefits under the plan as indicated. These products are Limited Coverage benefits but no Special Authority is needed. Please create a non-RDP code for these three products as this may be needed in the future when generics become available.

Please add max day of 30 days and maximum quantity to be dispensed of 56 tablets. DONE MV

September 22, 2011 – Please remove quantity limit from above drugs and keep max day supply. This was decided in consultation with EC. TF

DONE MV No mention of excluded plans however via telephone call with jillian Hardy excluded plans should be D S.

There was no 8% mark up included in the price (because that information was not in the DBR) however via email Sept 30 added as per Sophia & Tijana. MV sept 30/11

Grieve, Katie HLTH:EX

From: Arenson, Darlene H HLTH:EX
Sent: June-06-11 8:00 AM
To: Hardy, Jillian HLTH:EX; Margawang, Edmond HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX
Subject: Action Required - FW: Smoking cessation: how many attempt to succeed?

Jill/Ed

Please see Elaine's email below – she is requesting assistance from FM:

Would also be helpful to work with one of the FM pharmacists to do a scan of third-party payers (most of which have a lifetime limit – would be good to understand where they got this, and what the uptake has been among third party payers).

Is it possible to look into this today so that we can review the results at our DI- Smoking Cessation meeting tomorrow

Thank you
Darlene A
CDS

From: Chong, Elaine HLTH:EX
Sent: Saturday, June 4, 2011 8:32 AM
To: Pang, Walton HLTH:EX
Cc: Arenson, Darlene H HLTH:EX
Subject: RE: Smoking cessation: how many attempt to succeed?

Hi Walton,

Just reading through some other documents, and came across this great collection of resources:

http://www.health.gov.bc.ca/tobacco/resources.html

Within BC, BC Stats may also have some information. Shelley Canitz from QuitNow may also be a good resource.

In addition to my suggestion below, do you mind looking into some of these other resources?

EC

From: Chong, Elaine HLTH:EX
Sent: Fri, June 3, 2011 4:43 PM
To: Pang, Walton HLTH:EX
Cc: Arenson, Darlene H HLTH:EX
Subject: RE: Smoking cessation: how many attempt to succeed?

Walton,

Thanks for this – looks great.

Another way to look at this might be to search within the CADTH report – for the trials that evaluated varenicline and bupropion and NRTs, what were the # of quit attempts amongst patients? Were there any subgroup analyses that showed successful quitters had a certain # of previous quit attempts? Look at the key clinical trials instead of them all – you may have to pull some primary literature here.

While the population-based surveys are useful, I would like us to have a bit stronger stance (stronger evidence) if we are imposing a lifetime limit.

Would also be helpful to work with one of the FM pharmacists to do a scan of third-party payers (most of which have a lifetime limit – would be good to understand where they got this, and what the uptake has been among third party payers). **Darlene** – can you ask either Jill or Ed to assist?

EC

From: Pang, Walton HLTH:EX
Sent: Fri, June 3, 2011 4:11 PM
To: Arenson, Darlene H HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Galbraith, Susan HLTH:EX; Chong, Elaine HLTH:EX; Weston, Megan D HLTH:EX; Margawang, Edmond HLTH:EX; Hardy, Jillian HLTH:EX
Subject: Smoking cessation: how many attempt to succeed?

Hi Darlene:

Nice talking to you on the phone. You are interested in getting some support from the literature for the statement: "*smokers make 5 to 7 quit attempts before they successfully quit*"

Some support for the statement:

- Similar statements were used in multiple places, including the Centre for Tobacco Research and Intervention of the University of Wisconsin Medical School (http://www.ctri.wisc.edu/Smokers/Help%20Someone%20Quit%20Tobacco.pdf). However, no reference was cited.
- In a review article, Hughes stated that "*most smokers make **five to seven quit attempts** before they finally succeed. Thus half of all smokers eventually quit*."[1] However, the article cited by the author did not direct mention the "five to seven" numbers. Please note that Hughes published quite extensively on the topic of smoking cessation. (see attached)

To provide some Canadian context, a google search focused on published grey literature and results of surveys in Canada was conducted. Since participants of clinical trials may not be representative of the Canadian smoker population, biomedical databases were not used.

- Canadian Tobacco Use Monitoring Survey (CTUMS) 2003 - Fact Sheet – Quitting Smoking (Health Canada):
  *"Former smokers reported an average of **3.2 attempts to quit** before stopping for good, with males averaging more attempts (3.7) than did females (2.7)... About half of the former smokers reported quitting on their first attempt."*
- Canadian Tobacco Use Monitoring Survey (CTUMS) 2001 – Fact Sheet – Quitting Smoking Among Adults (Health Canada):
  *"Former smokers tried to stop an average **3.4 times** before succeeding, but the average number of quit attempts among those making more than one attempt was 6.1"*

- No recent data could be found
- The lower numbers (3 to 4, versus the “five to seven”) may be due to the high percentage of people who quitted on first attempts.
- Please also note that the definitions of “prolonged/continuous abstinence” and “quit attempt” may vary. Success also depends on the addiction level and baseline cigarette consumption and strategies used. I am wondering whether it’s possible to have “exact number”.

Reference

1. Hughes JR. New treatments for smoking cessation. CA Cancer J Clin 2000;50:143-51.

Please contact me if there’s any info you need.
<< File: 143.pdf >>
Walton Pang, BSc(Pharm), MSc, CAE
Pharmacist, Information
Drug Use Optimization | Pharmaceutical Services Division | BC Ministry of Health
303-960 Quayside Drive, New Westminster, BC V3M 6G2
t: 604.660.0582 |f 604.660.2108 |email: Walton.Pang@gov.bc.ca

---

From: Arenson, Darlene H HLTH:EX
Sent: Friday, June 3, 2011 1:18 PM
To: Pang, Walton HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Galbraith, Susan HLTH:EX; Chong, Elaine HLTH:EX; Weston, Megan D HLTH:EX; Margawang, Edmond HLTH:EX; Hardy, Jillian HLTH:EX
Subject: RE: Smoking cessation - DI subgroup, review of coverage scenarios, and follow-up items

Hi Walton

As per our phone discussion this afternoon thank you so much for agreeing to assist us on the literature search for the smoking cessation project to verify the following statement:

Number of quit attempts: It is normally quoted that smokers make 5 to 7 quit attempts before they successfully quit.

Walton – is it possible to have something prepared for end of day Wednesday June 8. Please let me know if this works for you

Thank you
Darlene A
CDS

(250) 952-1770

Grieve, Katie HLTH:EX

From: Margawang, Edmond HLTH:EX
Sent: July-07-11 9:21 AM
To: Chong, Elaine HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Hardy, Jillian HLTH:EX; Galbraith, Susan HLTH:EX; Weston, Megan D HLTH:EX; Arenson, Darlene H HLTH:EX; Rowe, Hilary HLTH:EX
Subject: Alberta coverage criteria for Champix
Attachments: Benefact #309 - Champix 2011june.pdf

Good morning, Elaine,

I would like to share the Alberta coverage criteria for Champix (attached) with the DI group.

We can learn from their criteria template.

I have also updated the provincial comparison database in the FM Access Restricted and Smoking SharePoint.

Regards,

Edmond Margawang, BSP, PharmD
Pharmacist Consultant, Formulary Management
Pharmaceutical Services Division
British Columbia Ministry of Health Services
Office: 250-952-3342
Edmond.Margawang@gov.bc.ca

Grieve, Katie HLTH:EX

From: Grieve, Katie HLTH:EX
Sent: September-30-11 3:57 PM
To: Grieve, Katie HLTH:EX; Arenson, Darlene H HLTH:EX; Fazlagic, Tijana HLTH:EX; Fowler, Sherrill A HLTH:EX; Hodges-Whittaker, Diane HLTH:EX; Phillips, Vivienne HLTH:EX; Tucker, Andrew HLTH:EX; Vetter, Daniel HLTH:EX; Bolzonello, Ed HLTH:EX; Bolzonello, Joanne HLTH:EX; Gordon, Jason HLTH:EX; Pollock, Lynn HLTH:EX; Weston, Megan D HLTH:EX; Chan, Dennis HLTH:EX; Chong, Elaine HLTH:EX; Lun, Eric HLTH:EX; Maynard, Kent HLTH:EX; Mira, Aileen HLTH:EX; Naumann, Terryn HLTH:EX; Shin, Sophia HLTH:EX; Tan, Dominic HLTH:EX; Taylor, Suzanne C HLTH:EX; Wan, Beverly HLTH:EX; Wilmer, Brett D HLTH:EX; Yamaguchi, Jesse HLTH:EX; Hardy, Jillian HLTH:EX; Voggenreiter, Christine HLTH:EX; Pang, Walton HLTH:EX; Margawang, Edmond HLTH:EX; Burke, Karen HLTH:EX; Galbraith, Susan HLTH:EX; Yamaguchi, Jesse HLTH:EX
Subject: CDR Submission Daily Update

Not Responsive

#2475 Champix (varenicline tartate) for Smoking Cessation
PSD Review Completed, Manufacturer Letter sent

Not Responsive

Page 35 redacted for the following reason:
- - - - - - - - - - - - - - - - - - - -
Not Responsive

Grieve, Katie HLTH:EX

From: Vetter, Daniel HLTH:EX
Sent: April-01-11 9:38 AM
To: Fazlagic, Tijana HLTH:EX
Subject: Champix - Submission 1650

Hi Tijana,

Just wondering why there is a PNet Date for Champix when under status it mentions

Received Date:	2007-May-04	CDR Drug Review:	Yes
Status:	Manufacturer submitted new information. PSD to review as resubmission		
Tentative Completion Date (Standard):		Tentative Completion Date (Complex):	

Kind Regards,
Dan

Grieve, Katie HLTH:EX

From: Chong, Elaine HLTH:EX
Sent: September-07-11 7:45 PM
To: Fazlagic, Tijana HLTH:EX
Cc: Chan, Dennis HLTH:EX; Lun, Eric HLTH:EX
Subject: DBN for varenicline

Hi Tijana,

Working on DBN tonight. Will you also include reference to safety info for varenicline in the DBN that FM is preparing (maybe as an Appendix)? Don't want to write a separate BN, so would be good if your team can incorporate. Some points for your consideration:

1) CADTH report safety info
2) DBC comment on safety (if any)?
3) Health Canada advisory on neuropsychiatric adverse effects
4) France decision to pull public coverage
5) CMAJ article (see Sept 6, 2011 issue) with meta-analysis on cardiovascular effects – methodologic limitations
6) Recent changes to varenicline product monograph to include stroke and cardiovascular labelling
7) Context of safety concerns (i.e., all safety info considered, and PSD decision is that benefits outweigh the risks)
8) Cross-jurisdictional scan (Alberta, Saskatchewan, Ontario, NWT, Quebec)

There may be a few more things, but that's what I can recall off the top of my head.

Thanks so much,
EC

Grieve, Katie HLTH:EX

From: Margawang, Edmond HLTH:EX
Sent: June-27-11 10:55 AM
To: Chong, Elaine HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Hardy, Jillian HLTH:EX; Galbraith, Susan HLTH:EX; Weston, Megan D HLTH:EX; Arenson, Darlene H HLTH:EX
Subject: FW: MedEffect e-Notice - Champix (varenicline tartrate) - Information Update

Good morning Elaine,

I thought that I would share this notice with you and DI group.

Regards,

Edmond Margawang, BSP, PharmD
Pharmacist Consultant, Formulary Management
Pharmaceutical Services Division
British Columbia Ministry of Health Services
Office: 250-952-3342
Edmond.Margawang@gov.bc.ca

From: medeffect-notice_avis-medeffet@HC-SC.GC.CA [mailto:medeffect-notice_avis-medeffet@HC-SC.GC.CA]
Sent: Monday, June 27, 2011 8:54 AM
To: MEDEFFECT@LIST.HC-SC.GC.CA
Subject: MedEffect e-Notice - Champix (varenicline tartrate) - Information Update

As a subscriber to Health Canada's MedEffect™ e-Notice, you are being informed of the latest Information Update.
http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2011/index-eng.php

Health Canada reviewing stop-smoking drug Champix (varenicline tartrate) and potential risk of heart problems in patients with heart disease

Health Canada is informing Canadians of an ongoing review of the smoking-cessation aid Champix (the

brand name for the prescription drug varenicline tartrate) and the possibility of a slightly increased risk of heart-related side effects in patients who have cardiovascular disease.

You can report any suspected adverse reactions to drugs and other health products to the Canada Vigilance Program by visiting the Reporting Adverse Reactions to Drugs and Other Health Products page.
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

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Grieve, Katie HLTH:EX

From: Shin, Sophia HLTH:EX
Sent: August-24-11 5:08 PM
To: Hodges-Whittaker, Diane HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Chong, Elaine HLTH:EX; Chan, Dennis HLTH:EX
Subject: PSFT

Hi Diane,

Just wondered if I could add the following topics to the PSFT agenda tomorrow (if they haven't already been added)?

Not Responsive

Bupropion (Zyban) & varenicline (Champix)

Could you please also forward the meeting invite with the call details, etc.?

Thanks,
Sophia

Grieve, Katie HLTH:EX

From: Lun, Eric HLTH:EX
Sent: June-06-11 11:34 AM
To: Cotton, Brian GCPE:EX
Cc: Jabs, Ryan GCPE:EX; Stewart, Michelle GCPE:EX; Nakagawa, Bob HLTH:EX; Fazlagic, Tijana HLTH:EX
Subject: Re: BC to Pay for Anti-Smoking Drug that France Finds too Risky

Follow Up Flag: Follow up
Flag Status: Completed

Brian - I'll ask Tijana to provide the chronology of our review and also ask her to provide provincial coverage details.

In terms of Health Authority coverage, some do cover but for continuity of care when patients come in on it or for long term care facilities. I'll send a spreadsheet with that info.

Eric

Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
Pharmaceutical Services Division, BC Ministry of Health Services

----- Original Message -----
From: Cotton, Brian GCPE:EX
Sent: Monday, June 06, 2011 10:21 AM
To: Lun, Eric HLTH:EX
Cc: Jabs, Ryan GCPE:EX; Stewart, Michelle GCPE:EX; Nakagawa, Bob HLTH:EX
Subject: RE: BC to Pay for Anti-Smoking Drug that France Finds too Risky

Hi Eric,

I'm trying to play catch-up since I haven't been involved in any of the materials around this so am I correct in saying that the drug has undergone a strict review process - CDR reviewed and recommended funding in 2009, BC then asked CADTH for a further review which was completed in ? and now DBC is currently reviewing varenicline for coverage and will have a decision before end of September 2011 since this is when the program is supposed to begin?

Also, how will this review from a HA perspective affect the outcome? Is it a totally separate review from DBC or will DBC consider any findings that may indicate there is a safety concern?
And who asked for that review?

Is it also correct to say Quebec is the only other province that covers vareniciline as part of their smoking cessation program?

I am going to put together an IN since the one we have is very limited so the more info I can get to understand this the better.

Thanks,
Brian

-----Original Message-----
From: Lun, Eric HLTH:EX
Sent: Monday, June 6, 2011 9:57 AM
To: Cotton, Brian GCPE:EX; Stewart, Michelle GCPE:EX; Nakagawa, Bob HLTH:EX
Cc: Jabs, Ryan GCPE:EX; May, Stephen GCPE:EX
Subject: Re: BC to Pay for Anti-Smoking Drug that France Finds too Risky

No, CDR first reviewed in ?2009 or so and recommended funding. We then asked CADTH to complete a further comparative review on it, buproprion and NRTs. And most recently, before bringing to DBC in April, we asked the manufacturer to provide saftey update.
So, we should be quite current with safety awareness.

Having said that, Aaron Tejani who also does contract work for TI is also assessing from Health Authority perspective. I am aware that he is concerned about safety.

Eric

Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
Pharmaceutical Services Division, BC Ministry of Health Services

----- Original Message -----
From: Cotton, Brian GCPE:EX
Sent: Monday, June 06, 2011 09:43 AM
To: Lun, Eric HLTH:EX; Stewart, Michelle GCPE:EX; Nakagawa, Bob HLTH:EX
Cc: Jabs, Ryan GCPE:EX; May, Stephen GCPE:EX
Subject: RE: BC to Pay for Anti-Smoking Drug that France Finds too Risky

Hi Eric,

Just out of curiosity, was the Therapeutics Initiative involved in reviewing Varenicline?

Thanks,
Brian

-----Original Message-----
From: Lun, Eric HLTH:EX
Sent: Monday, June 6, 2011 9:38 AM
To: Stewart, Michelle GCPE:EX; Nakagawa, Bob HLTH:EX
Cc: Cotton, Brian GCPE:EX; Jabs, Ryan GCPE:EX; May, Stephen GCPE:EX
Subject: Re: BC to Pay for Anti-Smoking Drug that France Finds too Risky

I'll try to dig up the risk number.

Overall, I agree with the approach by Bob but to emphasize that all products have risks and benefits. Varenicline is efficacious (actually more than NRTs) but has some known risks that should be weighed by the patient and prescribing physician and monitored if prescribed.

Eric

Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
Pharmaceutical Services Division, BC Ministry of Health Services

----- Original Message -----
From: Stewart, Michelle GCPE:EX
Sent: Monday, June 06, 2011 08:24 AM
To: Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX
Cc: Cotton, Brian GCPE:EX; Jabs, Ryan GCPE:EX; May, Stephen GCPE:EX
Subject: RE: BC to Pay for Anti-Smoking Drug that France Finds too Risky

Ok will wait for eric to wade in....and yes...if there is some reconsideration of the drug in light of the decision in France would be good to know now

Michelle Stewart, Communications Director
Ministry of Health, Government Communications & Public Engagement
Phone: 250-952-1889 Cell: s.17 Fax: 250-952-1883
Michelle.Stewart@gov.bc.ca

-----Original Message-----
From: Nakagawa, Bob HLTH:EX
Sent: Monday, June 6, 2011 7:23 AM
To: Stewart, Michelle GCPE:EX; Lun, Eric HLTH:EX
Cc: Cotton, Brian GCPE:EX; Jabs, Ryan GCPE:EX; May, Stephen GCPE:EX
Subject: Re: BC to Pay for Anti-Smoking Drug that France Finds too Risky

Yes, both varenicline and bupropion will be covered, as well as the NRTs
Bob Nakagawa, ADM
Pharmaceutical Services Division
BC Ministry of Health Services
250.952.1705

----- Original Message -----
From: Stewart, Michelle GCPE:EX
Sent: Monday, June 06, 2011 07:18 AM
To: Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX
Cc: Cotton, Brian GCPE:EX; Jabs, Ryan GCPE:EX; May, Stephen GCPE:EX

Subject: RE: BC to Pay for Anti-Smoking Drug that France Finds too Risky

with respect to the drug component - have we actually landed on what we're covering...

_____

From: Nakagawa, Bob HLTH:EX
Sent: Monday, June 06, 2011 7:15 AM
To: Stewart, Michelle GCPE:EX; Lun, Eric HLTH:EX
Cc: Cotton, Brian GCPE:EX; Jabs, Ryan GCPE:EX; May, Stephen GCPE:EX
Subject: Re: BC to Pay for Anti-Smoking Drug that France Finds too Risky

Initial thoughts:
Drug approved by Health Canada and reviewed by the Drug Benefit Council and CDR who considered the evidence in detail, and considered these drugs to be reasonable options for consideration
These are prescription drugs, so MDs will be able to consider and monitor for any adverse effects
Eric, can you confirm what the incidence rate is for the ADRs? I suspect that they are quite small due to the large numbers of patients
We want to be careful in this, as it wouldn't look good if varenicline were to be withdrawn from the Canadian Market after we defend its safety

B

Bob Nakagawa, ADM
Pharmaceutical Services Division
BC Ministry of Health Services
250.952.1705

----- Original Message -----
From: Stewart, Michelle GCPE:EX
Sent: Monday, June 06, 2011 06:53 AM
To: Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX
Cc: Cotton, Brian GCPE:EX; Jabs, Ryan GCPE:EX; May, Stephen GCPE:EX
Subject: FW: BC to Pay for Anti-Smoking Drug that France Finds too Risky

Bob/Eric...see story below....thoughts?

s.3

Pages 45 through 48 redacted for the following reasons:
- -
s.3

Grieve, Katie HLTH:EX

From: Chong, Elaine HLTH:EX
Sent: December-17-10 10:47 AM
To: Fazlagic, Tijana HLTH:EX
Cc: Zimmerman, Janine HLTH:EX; Guiltenane, Erin HLTH:EX
Subject: RE: Champix binder contents from Pfizer

Tijana,

Done – saved to this target location. I'll bring over the CD next time, and Eric will bring over a hard copy of the binder. I also have an additional hard copy of the binder that I will keep for now.

EC

From: Fazlagic, Tijana HLTH:EX
Sent: Friday, December 17, 2010 8:04 AM
To: Chong, Elaine HLTH:EX; Lun, Eric HLTH:EX; Guiltenane, Erin HLTH:EX
Cc: Zimmerman, Janine HLTH:EX
Subject: RE: Champix binder contents from Pfizer

Hi Elaine,

Thanks for asking. Please save it in X:\Formulary Management - Access Restricted\Drugs - CDR - Common Drug Review\Champix\Champix 2475.

Tijana

Tijana Fazlagic , B.Sc.(Pharm), MSc
Director
Formulary Management
Pharmaceutical Services
(250) 952-1475
Tijana.Fazlagic@gov.bc.ca

From: Chong, Elaine HLTH:EX
Sent: Thursday, December 16, 2010 11:13 PM
To: Lun, Eric HLTH:EX; Guiltenane, Erin HLTH:EX
Cc: Zimmerman, Janine HLTH:EX; Fazlagic, Tijana HLTH:EX
Subject: RE: Champix binder contents from Pfizer

Will do.

Tijana – is there a specific place on Coral you would like me to place this information?

EC

From: Lun, Eric HLTH:EX
Sent: Thursday, December 16, 2010 7:48 PM
To: Guiltenane, Erin HLTH:EX
Cc: Zimmerman, Janine HLTH:EX; Chong, Elaine HLTH:EX; Fazlagic, Tijana HLTH:EX
Subject: Re: Champix binder contents from Pfizer

Thanks Erin. Pls pass to Elaine.

Elaine - can you copy the files to a location on the FM site so Tijana and others can access? This is resub material so it needs to be properly files.

Thanks,
Eric

Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
Pharmaceutical Services Division, BC Ministry of Health Services

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From: Guiltenane, Erin HLTH:EX
Sent: Thursday, December 16, 2010 01:31 PM
To: Lun, Eric HLTH:EX
Cc: Zimmerman, Janine HLTH:EX
Subject: Champix binder contents from Pfizer

Hi Eric,

An express envelope arrived for you today with the a CD marked **BC-CD CHAMPIX, binder contents from Dec 10, 2010, meeting with Chris Smith**. I've date-stamped the envelope. Since this arrived express, I was wondering if you need it urgently?

Thanks,

Erin

Erin Guiltenane

Administrative Assistant
Drug Use Optimization - Pharmaceutical Services Division
BC Ministry of Health Services
T: **(604) 660-1978** F: (604) 660-2108

Grieve, Katie HLTH:EX

From: Chong, Elaine HLTH:EX
Sent: June-17-11 4:36 PM
To: Shin, Sophia HLTH:EX; Margawang, Edmond HLTH:EX; Lun, Eric HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Arenson, Darlene H HLTH:EX; Hardy, Jillian HLTH:EX; Galbraith, Susan HLTH:EX; Tan, Dominic HLTH:EX; Chan, Dennis HLTH:EX
Subject: RE: Champix Update

Hello all,

Further to the emails below, I looked into the new FDA advisory of varenicline-associated cardiovascular adverse events in patients with cardiovascular disease (post-marketing surveillance showing more events compared to placebo, including nonfatal MI, need for coronary revascularization, angina, and peripheral vascular disease). Product labelling will be changed in the US.

http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106540.htm

There is nothing yet from Health Canada.

FYI, from looking at the Health Canda website, I note that pioglitazone Actos is now being reviewed by Health Canada for its link to bladder cancer – **Tijana**, can your team flag this for an update during our ongoing diabetes review.

EC

From: Chong, Elaine HLTH:EX
Sent: Friday, June 17, 2011 1:43 PM
To: Shin, Sophia HLTH:EX; Margawang, Edmond HLTH:EX; Lun, Eric HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Arenson, Darlene H HLTH:EX; Hardy, Jillian HLTH:EX; Galbraith, Susan HLTH:EX; Tan, Dominic HLTH:EX
Subject: FW: Champix Update

All,

See below. Varenicline is now listed in Alberta, as of June 15, 2011. It is an SA drug, with the following criteria:

This coverage is a restricted benefit; only those plan members who are (1) 18 years of age and older, (2) on a government-sponsored supplementary health plan and (3) enrolled in an Alberta Health Services tobacco-cessation program (AlbertaQuits Helpline and/or AlbertaQuits Groups) will be eligible to receive coverage for Champix®.

Detailed information about the operational program model, as well as pharmacy logistics are described in this email chain below.

Edmond – I know you are busy covering for FM this week, but I am hoping you can survey our colleagues in the other jurisdictions to see if any other province is close to announcing coverage, and if so, with what criteria? Please update the jurisdictional scan on SP once you have completed your survey – hoping to have some results before next week's working group meeting.

Thanks all,
EC

From: Smith, Christopher C [mailto:Christopher.C.Smith@pfizer.com]
Sent: Friday, June 17, 2011 12:35 PM
To: Chan, Dennis HLTH:EX; Chong, Elaine HLTH:EX
Cc: Dawson, Bob
Subject: Champix Update

Elaine and Dennis:

I have been on the road and wanted to provide you with the most up to date information regarding some recent developments. The following is Pfizer's recent statement regarding the FDA and information on the Alberta Government's decision to provide coverage for Champix.

If you have any further questions, please don't hesitate to contact me.

Chris

Pfizer Statement

Pfizer has studied CHANTIX®/CHAMPIX® (varenicline) in a randomized, double-blind, placebo-controlled clinical trial in smokers with certain types of cardiovascular disease (CVD). These clinical study data were submitted to FDA and were published in the journal *Circulation* (Vol 121, No 2, January 2010). The overall cardiovascular event rates reported in the study were low, but there was a small, increased incidence of certain cardiovascular events in patients taking CHANTIX/CHAMPIX compared to patients taking placebo. FDA is requesting a large, combined analysis (meta-analysis) of existing CHANTIX/CHAMPIX clinical data to evaluate the cardiovascular safety of CHANTIX/CHAMPIX. Pfizer will be discussing the details of the meta-analysis, as well as the product labelling with the FDA.

As stated by the FDA, patients should contact their healthcare professional if they experience new or worsening symptoms of cardiovascular disease. Smoking is a major public health issue - it is the leading cause of premature death in Canada[i].Smoking is a major risk factor for cardiovascular disease (CVD), which can lead to heart attack, stroke and peripheral arterial disease. The health benefits of quitting smoking are immediate and substantial.[ii]

Approximately 1.3 billion people worldwide smoke cigarettes[iii]. Each year, an estimated 5.4 million people die from smoking related causes[iv].

Medical treatments, including CHANTIX/CHAMPIX, are helpful with assisting smokers motivated to quit.

Pfizer takes patient safety very seriously. Pfizer works with health agencies worldwide to monitor and review all sources of data for CHANTIX/CHAMPIX on a continual basis.

Smoking in Canada

In Canada, 18 per cent of the population aged 15 years and older smoke.[v] This year more than 37,000 Canadians will die due to smoking, making it a major public health issue.[vi] In fact, according to Health Canada, close to half of all smokers will die from smoking before they turn 70 years old.[vii]

In health care, tobacco use costs Canada billions of dollars each year. Despite the reduced rate of smoking, health care costs have increased steadily since 1966.[viii] In 2002, tobacco use accounted for $17 billion in health care costs including $12.5 billion in indirect costs such as lost productivity, longer-term disability and premature death.[ix]

Canadian healthcare professionals looking for additional medical information can review the CHAMPIX Product Monograph or contact Pfizer medical information at 1 800 463 6001. We encourage any patients with questions about whether or not CHAMPIX is right for them to consult with their healthcare provider.

-30-

EFFECTIVE JUNE 15, 2011
Alberta Health and Wellness Drug Benefit List (AHWDBL)

Effective June 15, 2011, members of Alberta government-sponsored supplementary health plans are eligible to receive coverage for Champix® (Varenicline Tartrate). This coverage is a restricted benefit; only those plan members who are (1) 18 years of age and older, (2) on a government-sponsored supplementary health plan and (3) enrolled in an Alberta Health Services tobacco-cessation program (AlbertaQuits Helpline and/or AlbertaQuits Groups) will be eligible to receive coverage for Champix®.

Any member of the Alberta government-sponsored supplementary health plans who wish to quit tobacco using Champix® must show proof of enrolment in an Alberta Health Services tobacco-cessation program in order to fill a prescription for Champix®.

In order to get the prescription initially and then get refills at four and at eight weeks, the individual must follow the following steps:

1. The individual will visit his/her physician to receive a prescription for Champix®.
2. In addition to providing the patient with a prescription, the physician will refer the patient to an Alberta Health Services tobacco-cessation program.

3. The patient will enrol in an Alberta Health Services tobacco-cessation program.
4. The patient will request an intervention form from the tobacco-cessation program.
5. The patient will present the form to a pharmacist and receive up to a four-week supply of Champix® medication. (Initially a single starter pack is allowed).

6. Prior to each prescription fill, renewed on a four-week basis, the patient must request a letter of confirmation of continued enrolment from the tobacco-cessation program.

7. The patient will provide his/her pharmacist with the prescription and the letter of enrolment when having the drug refilled and will repeat steps 6 and 7 for continued tobacco-cessation therapy.

Pharmacists will need to document on the patient's file that they have confirmed the patient is enrolled in a program for future post-claim verification upon request.

Three forms have been created to assist health care professionals and patients:

1. Healthcare Professional Information for Prescribing Champix® (varenicline tartrate) for Subscribers of Government-Sponsored Supplementary Health Plans;

2. Patient Information - Receiving Champix® under your Government-sponsored Supplementary Health Plan; and
3. Champix® Intervention Proof-of-Enrolment Form.

Form 1 is intended to be used by physicians and provides detailed information on who is eligible for this initiative, what tobacco-cessation programs can be utilized and the steps that should be followed by patients.

Form 2 is meant to be distributed to patients to assist them in following the proper steps to receive their medication.

Form 3 will be distributed by Alberta Health Services tobacco-cessation programs to patients as proof of enrolment.

<> <> <>

Plan members enrolled in a listed Alberta Health Services tobacco-cessation program must provide their Alberta Health Services proof-of-enrolment form confirming participation along with their prescription for Champix®.

Pharmacists will need to use an intervention code of **UF – patient gave adequate explanation, prescription filled as written** on the direct-bill claim to identify that the plan member has enrolled in a cessation program. If plan members are not participating in a listed program, they are not eligible for Champix®. As a result, the claim will be rejected, stating **CD – patient not entitled to drug claimed.**

A quantity limit will be placed on this product; the maximum amount eligible per dispense will be

> 14-day supply (25 tablets) for the starter pack (DIN 02298309) or
> 28-day supply (56 tablets) for the continuation therapy (either DIN 02291185, 1 mg blister pack of 28 tablets x 2, or DIN 02291177, 0.5mg bottle up to 112 tablets).

Serious Warnings and Precautions
Some post-marketing reviews report serious neuropsychiatric symptoms in patients being treated with Champix® (Varenicline Tartrate). These symptoms include depressed mood, agitation, aggression, hostility, changes in behaviour and suicide-related events, including ideation, behaviour, attempted suicide and suicide, as well as worsening of pre-existing psychiatric disorder. These events have occurred in patients with and without pre-existing psychiatric disorders (see also WARNINGS AND PRECAUTIONS, Psychiatric Symptoms).

Chris Smith I Manager, British Columbia -- Government, Patient Access, Health Policy

Pfizer Canada Inc.
17300 Trans Canada, Kirkland, Qc, H9J 2M5 **I** Tel: 778-430-5833 **I** Fax: 778-430-5844 **I** Cell: 250-634-0660

pfizer.ca

What can we do to stay healthy?
Visit morethanmedication.ca for tips, advice and helpful hints

Grieve, Katie HLTH:EX

From: Lun, Eric HLTH:EX
Sent: December-21-10 10:56 AM
To: Fazlagic, Tijana HLTH:EX; Chong, Elaine HLTH:EX; Vetter, Daniel HLTH:EX
Subject: RE: Champix

I think for this, we have flexibility to approach it as we like. If it is easier to review together then we can. So, we could lump in the NRT into the TR as Tijana suggested.
Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
Pharmaceutical Services Division, BC Ministry of Health Services

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From: Fazlagic, Tijana HLTH:EX
Sent: Tue 21/12/2010 10:50 AM
To: Chong, Elaine HLTH:EX; Vetter, Daniel HLTH:EX
Cc: Lun, Eric HLTH:EX
Subject: RE: Champix

We have a separate submission for NRT which was received recently, so I think that should be included as part of TR rather than separately.

Tijana Fazlagic , B.Sc.(Pharm), MSc
Director
Formulary Management
Pharmaceutical Services
(250) 952-1475
Tijana.Fazlagic@gov.bc.ca

From: Chong, Elaine HLTH:EX
Sent: Tuesday, December 21, 2010 10:46 AM
To: Fazlagic, Tijana HLTH:EX; Vetter, Daniel HLTH:EX
Cc: Lun, Eric HLTH:EX
Subject: RE: Champix

Tijana and Dan – I thought varenicline was going through as part of the TR, as we don't actually have a separate submission for NRT or bupropion?

Eric – Do you agree?

EC

From: Fazlagic, Tijana HLTH:EX
Sent: Tuesday, December 21, 2010 10:05 AM
To: Chong, Elaine HLTH:EX; Vetter, Daniel HLTH:EX
Subject: RE: Champix

Hi Elaine,

With regards to this review, main question in my mind is whether we approaching varenicline and NRT as separate drug submissions or is it all going under the smoking cessation therapeutic review? Depending on answer to this question, DRRC/DRRT requirements would differ. I was under the impression that we are approaching it as a therapeutic review, but I could be wrong.

Tijana

Tijana Fazlagic , B.Sc.(Pharm), MSc
Director
Formulary Management
Pharmaceutical Services
(250) 952-1475
Tijana.Fazlagic@gov.bc.ca

From: Chong, Elaine HLTH:EX
Sent: Tuesday, December 21, 2010 9:30 AM
To: Vetter, Daniel HLTH:EX; Fazlagic, Tijana HLTH:EX
Subject: RE: Champix

Dan,

Is this going forward with the CADTH therapeutic review, which will also cover bupropion and the NRTs?

What info do you need from me for the DRRTs? Wouldn't you put this through the usual process? Sorry if I'm not understanding your request here.

Eric also asked me to put together a survey for the HA – Eric still needs to sign-off on this survey template before it goes out to the HA (see attached email). Would suggest that we use a similar kind of template (as we've done for the other TR) to help gather feedback on our key policy questions. What do you and Tijana think?

EC << Message: FW: Smoking Cessation Program Template for HA > For Your Review >>

From: Vetter, Daniel HLTH:EX
Sent: Tuesday, December 21, 2010 9:14 AM
To: Chong, Elaine HLTH:EX
Subject: Champix

Hi Elaine,

What work needs to be performed by the DRRTs? We have tentatively slated for April DBC and I would like assign possibly at Jan 10th DRRC Meeting.

FYI – The binder is here in Victoria

Kind Regards,

Dan

Grieve, Katie HLTH:EX

From: Zimmerman, Janine HLTH:EX
Sent: September-20-11 9:07 AM
To: Fazlagic, Tijana HLTH:EX; Chong, Elaine HLTH:EX
Subject: RE: GCPE request - Additional QAs - Prescription drugs

Hi Elaine,

Eric has approved with changes. See attached.

Name	QA NRT RollOut Sept11 9pm
Title	Questions and Answers
Approval	Approved with Changes
Description Comments	GCPE Request from Elaine for your approval. Tijana has reviewed - see email.
ED Comments	

Created at 9/19/2011 3:17 PM by Zimmerman, Janine HLTH:EX
Last modified at 9/19/2011 4:55 PM by Lun, Eric HLTH:EX

Janine Zimmerman
Executive Assistant
Drug Intelligence
Pharmaceutical Services
250 952-2504

From: Fazlagic, Tijana HLTH:EX
Sent: Monday, September 19, 2011 3:02 PM
To: Chong, Elaine HLTH:EX; Zimmerman, Janine HLTH:EX
Subject: RE: GCPE request - Additional QAs - Prescription drugs

Hi Elaine and Janine,

I have made some minor changes to first three questions below.

Janine,

Please post this to Eric's SharePoint as urgent as Elaine needs it approved ASAP.

Thank you,

Tijana

From: Chong, Elaine HLTH:EX
Sent: Mon, September 19, 2011 11:33 AM
To: Fazlagic, Tijana HLTH:EX
Cc: Zimmerman, Janine HLTH:EX
Subject: FW: GCPE request - Additional QAs - Prescription drugs

Tijana,

Can you please edit these FAQs and then Janine can post as urgent on Eric's SP? We need to get these back to GCPE ASAP.

EC

From: Chong, Elaine HLTH:EX
Sent: Tue, September 13, 2011 9:47 AM
To: Fazlagic, Tijana HLTH:EX; Lun, Eric HLTH:EX
Cc: Zimmerman, Janine HLTH:EX
Subject: GCPE request - Additional QAs - Prescription drugs

Tijana and Eric,

Thought I could get to editing these FAQs prior to sending to you, but just have just been putting out fires for the last 24 hours or so. So sorry – haven't revised these yet.

Can you please revise and approve these FAQs re: the drug review process and safety issues for varenicline and bupropion? Please see the full questions in the attachment.

EC

From: Porter, Rodney GCPE:EX
Sent: Sun, September 11, 2011 9:06 PM
To: Chong, Elaine HLTH:EX
Subject: Additional QAs - Prescription drugs

Elaine;

I have been asked to include some QAs about the two prescription drugs. Highlighted in the attachment. If you could review, that would be great. Thanks.

Also, I have included the laser therapy questions which I know came up a while back.
<< File: QA_NRT_RollOut_Sept11_9pm.docx >>

Q. What steps did we take to review the drugs?

The Ministry drug coverage decisions are made through its rigorous drug review process which considers clinical evidence, cost-effectiveness, input from clinical experts, patient input, information from other jurisdictions, available resources and existing programs and policies.

Varenicline and bupropion are already covered in other provinces and territories, such as Alberta, Saskatchewan, Ontario, Quebec and Yukon.

Q. How did we decide that the benefits from taking these drugs outweigh the risks?

All decisions are made on best clinical evidence.
Neither of these drugs are available over the counter so it is necessary for a conversation to happen between a patient and doctor who together can determine whether or not these drugs are appropriate.
The final decision measures safety concerns against clinical evidence that shows the benefit of the drug in patients trying to quit smoking

Q. Will you continue to monitor the safety of these drugs?

Patient safety is always paramount. Varenicline and bupropion may cause neuropsychiatric adverse events. Varenicline is may be associated with cardiovascular events.
As with all prescription drugs, we will continue to monitor evidence as it becomes available.
All patients who use prescription drugs must consult with their doctor first before being prescribed any medications. They will be closely monitored by their doctor to ensure that there are no concerns.
Anyone who experiences any adverse symptoms when taking these drugs, or any drug for that matter, should stop taking the drug and consult a doctor immediately.

Q. Why did you not look at alternative therapies such as laser therapy?

PharmaCare would not cover laser therapy as it is not considered a prescription drug or medical supply.
For government to consider coverage of laser therapy or acupuncture as part of its smoking cessation program, additional evidence regarding its efficacy, safety, and cost-effectiveness are required.
The Ministry is pleased to continue discussions with the laser therapists program should additional evidence of efficacy, safety and cost-effectiveness become available, particularly in the Canadian context.

Rodney Porter, Communications Manager
Ministry of Health, Province of B.C.
T: 250 952-1644
C: s.17
rodney.porter@gov.bc.ca

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QUESTIONS AND ANSWERS

Roll-out of the B.C. Ministry of Health Smoking Cessation Program

Ministry of Health
September X, 2011

Draft: Sept 11, 9pm

Q. What does the B.C. Smoking Cessation Program include?

- The program helps B.C. residents stop smoking or stop using other tobacco products by assisting them with the cost of a number of different types of smoking cessation aids:
  - eligible non-prescription (over-the-counter) nicotine replacement therapy
    - chewing gum **or**
    - patches **or**
  - prescription smoking cessation drugs
    - bupropion (brand name Zyban) **or**
    - varenicline (brand name Champix).
- Each calendar year (January 1 through December 31), eligible B.C. residents can get coverage for either one nicotine replacement therapy product or one prescription drug for a single continuous course of treatment lasting up to 12 continuous weeks.

Q. How long will this program run for?

- The program begins September 30, 2011.
- While there is no planned end date, the Ministry of Health will monitor the uptake and effectiveness of the program and refine whenever possible.

Q. Who will be eligible?

- The program is open to B.C. residents who wish to stop using tobacco. All British Columbian smokers and other tobacco users with active coverage through the province's Medical Services Plan are eligible for nicotine replacement therapy products such as gum and patches.
- Prescription drugs will be covered through PharmaCare, so people will have to be enrolled in one of the PharmaCare plans to have their prescription drug costs covered. Most people will be covered through Fair PharmaCare, the income-based plan that any B.C. resident can enrol in. The usual PharmaCare plan rules apply.

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QUESTIONS AND ANSWERS

Q. How do British Columbians access coverage for the NRTs?

- BC residents can register for NRT coverage by calling HealthLink BC at 8-1-1.
- They will then be asked a number of questions, including their Care Card Personal Health Number, during the registration process.
- Clients will be given a choice of having the NRT mailed to them or they will get a reference number that they take to a community pharmacy that will provide 100% coverage for the product (that is, free-of-charge).
- Clients will receive a 28-day supply of the NRT product at a time, up to a maximum of three fills of 28 days each (12 consecutive weeks or 84 consecutive days).
- By calling HealthLink BC at 8-1-1, clients will also be offered additional information and support, including counselling through QuitNow Services

Q. Why did you select this distribution model for the NRTs?

- The hybrid distribution (through direct mail and through community pharmacies) offers client choice and convenience.
- HealthLink BC is a consortium of recognized health information services, including Nursing Services, Pharmacist Services (after-hours), Dietitian Services, and the BC HealthGuide. HealthLink BC is available by phone in over 130 different languages 24/7/365.
- The direct mail service is offered through the province's Product Distribution Centre which is a government service under the Ministry of Labour, Citizens' Services and Open Government.

Q. How do British Columbians access coverage for the prescription smoking cessation drugs bupropion and varenicline?

- BC residents can visit their physician to discuss the prescription smoking cessation drugs bupropion and varenicline.
- Prescriptions for these drugs can be filled at any community pharmacy, as is usually the case with any prescription drug.
- These drugs will only be available by prescription.

Q. How will the prescription drugs be distributed?

- As is the case with any prescription drug, bupropion and varenicline will only be available by prescription through community pharmacies.

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~~\\drill\kagrieve$\profile\desktop\foi\27a.docxhttps://hlth004.gov.bc.ca/PSD/DI/ED Document Review/Urgent Documents/QA_NRT_RollOut_Sept11_9pm.docx~~~~k:\3 policy outcomes, evaluation & research\project - communications\2011-008 smoking cessation coverage\qa_nrt_rollout_aug29_2pm dm pl edits.docx~~

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QUESTIONS AND ANSWERS

Q. What about those British Columbians – like some Downtown Eastside residents – who stand to benefit the most but are not registered with MSP?

- Registration with MSP is easy and only takes a couple of days to set up an account.
- For clients with no permanent mailing address, an account can still be set up.

Q. Why is the access to NRTs and prescription drugs for up to 12 weeks?

- We want to help maximize people's chances of success. Clinical studies show that people are more likely to successfully quit smoking after sticking to a course of treatment for 12 weeks in a row.

Q. Why are you only dispensing 28 days worth of NRTs or prescription drugs at a time?

- 28 days worth of NRTs are mailed out at a time with renewals sent upon request up to a maximum of 12 consecutive weeks' worth (84 consecutive days).
- We limit each fill to 4 weeks (28 days) in case clients need to make changes to the dose or product or medication, or the client decides to stop treatment. This will minimize the cost of unused medications. ~~at way neither you nor we will have had to pay for medication that can't be used.~~
- We also limit the supply because not all clients need a full 12-week course of treatment to be able to quit. Some people can quit with less NRTs or prescription drugs.

Q. Why did you decide to make eligibility for prescription smoking cessation drugs only for people who qualify through PharmaCare?

- The B.C. PharmaCare program helps eligible British Columbia residents with the costs of eligible prescription drugs and designated medical supplies. It normally does not cover non-prescription (over-the-counter medications) such as nicotine replacement therapy products.
- PharmaCare covers the prescription smoking cessation drugs bupropion (brand name Zyban) and varenicline (brand name Champix) in exactly the same way as all other eligible prescription drugs. Depending on the PharmaCare plan a person is enrolled in, PharmaCare may cover all or part of their cost. Individuals and families with low income families will usually not have to pay anything for the 12-week course of prescription drug treatment.
- Nicotine replacement therapy products are being offered at no charge to help clients who want to stop smoking but who, for whatever reason, may not be able or willing to take the prescription drugs. The Ministry believes it is essential to provide these British Columbians the help they need to stop smoking and get healthy.
- Under the program, all British Columbians will get help from the government to quit smoking through access to a 100%-covered course of nicotine replacement therapy.

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~~\\drill\kagrieve$\profile\desktop\foi\27a.docxhttps://hlth004.gov.bc.ca/PSD/DI/ED Document Review/Urgent Documents/QA_NRT_RollOut_Sept11_9pm.docx\3 policy outcomes, evaluation & research\project - communications\2011-008 smoking cessation coverage\qa_nrt_rollout_aug29_2pm dm pl edits.docx~~

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QUESTIONS AND ANSWERS

Q. How will you prevent fraud?

- We want to make the program easily accessible to everyone who wants to participate but at the same time want to ensure it is not misused.
- ~~This was one of the issues that was considered during the consultation on how to implement the program, and t~~There are a number of ways that clients will be held accountable when they participate in the program.
- Clients will be required to provide their Care Card Personal Health Number when registering for coverage of NRTs. The personal health number can be used to confirm the person's Medical Services Plan status and thus their B.C. residency.
- Clients can only receive a certain amount of NRT gum or patches – a supply of up to 12 weeks will be provided once a year to eligible B.C. residents who register for the program.
- Clients who are provided with NRT products through this program will have the NRTs recorded on their PharmaNet profile.
- The Ministry of Health will monitor the uptake and efficiency~~ectiveness~~ of the program and refine whenever possible. The Ministry will also work with health care professionals (doctors, pharmacists, HealthLink BC, others) to ensure that clients are held accountable.
- ~~We want to make the program easily accessible to everyone who wants to participate but at the same time want to ensure it is not misused.~~

Q. What other provinces cover the costs of smoking cessation aids?

- As of Sept. 6, 2011, coverage for NRTs is available in Quebec and the Northwest Territories, in addition to B.C.
- As of September 6, 2011, coverage for the prescription smoking cessation drugs (bupropion and varenicline) is available in Alberta, Saskatchewan, Ontario, Quebec, and the Northwest Territories.
- Coverage for smoking cessation aids is under review in other provinces and territories.

Q. What is the cost of the program? ~~Have you a better estimate of the cost?~~

- The total cost estimate for the program – including NRTs and prescription drugs – is still between $15 million and $25 million.
- The final cost will depend on how many people choose to take advantage of the program. We know that not all smokers will participate as quitting is dependent on being motivated.

Q. How much revenue is collected from tobacco?

- In 2009/10, revenue from tobacco was $682 million.

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- An estimate of the costs associated with tobacco use in BC for 2002 is $2.3 billion, including $605 million for direct health care costs

Q. What about Health Canada's safety information about the adverse effects of varenicline (brand name Champix)?

- All drugs have potentials risks and potential benefits.
- As with all prescription drugs, you need to check with your health professional about what is best for you. You need to balance the pros against the cons.

Q. What steps did we take to review the drugs?

- The Ministry drug coverage decisions are made through its rigorous drug review process which considers clinical evidence, cost-effectiveness, input from clinical experts, information from other jurisdictions, available resources and existing programs and policies.
- Varenicline and bupropion are already covered in other provinces, such as Alberta, Saskatchewan, Ontario and Quebec. Both drugs have already been reviewed and recommended for funding by the National Common Drug Review.

Q. How did we decide that the potential benefits from taking these prescription drugs (varenicline and bupropion) outweigh the potential risks?

- All decisions are made on best clinical evidence.
- Neither of these drugs are available over the counter so it is necessary for a conversation to happen between a patient and doctor who together can determine whether or not these drugs are appropriate.
- The final decision measures safety concerns against clinical evidence that shows the benefit of the drug in patients trying to quit smoking
- The Ministry will continue to monitor any new clinical information and adjust its coverage as appropriate.

Q. Will you continue to monitor the safety of these prescription drugs?

- Patient safety is always paramount.
- As with all prescription drugs, we will continue to monitor evidence as it becomes available.
- All patients who use prescription drugs must consult with their doctor first before being prescribed any medications. They will be closely monitored by their doctor to ensure that there are no concerns. Anyone who experiences any adverse symptoms when taking these

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drugs, or any drug for that matter, should stop taking the drug and consult a doctor immediately.

- Bullet on : Health Canada's drug safety monitoring program

Q. Are other smoking cessation therapies besides drugs, like laser therapy covered? ~~Why did you not look at alternative therapies such as laser therapy?~~

- PharmaCare covers only drugs and certain medical supplies. ~~would not cover laser therapy as it is not considered a prescription drug or medical supply.~~
  - Laser therapy and acupuncture are not currently covered as part of the program. For government to consider coverage of laser therapy or acupuncture as part of its smoking cessation program, additional evidence regarding its efficacy, safety, and cost-effectiveness are required.
  - The Ministry is pleased to continue discussions with the laser therapists program should additional evidence of efficacy, safety and cost-effectiveness become available, particularly in the Canadian context.

Q. Your original commitment indicated that physicians would be able to have a discussion with their patients about smoking cessation - how ~~much~~ will physicians be paid for having ~~this~~ smoking cessation discussions with their patients~~.~~?

- There are two ways physicians may bill to have smoking cessation discussions with their patients:
- Physicians may do brief interventions for tobacco cessation during a regular office visit (series 0100) when the patient is already seeing the physician for another medical reason (fee is approximately ~~worth~~ $30). If a patient only comes to see a physician to discuss tobacco cessation then the physician cannot bill for the office visit.
- If a patient has any one of the following risk criteria (smoker, unhealthy eater, physically inactive, obese) their physician may conduct a Personal Health Risk Assessment visit (14066) whereby they have a discussion about prevention interventions as listed in the BC Prevention Schedule for Life (of which quitting smoking is one of these interventions). The $50 fee for this service has been available since Jan. 1, 2011. **[NOTE: This is the fee billable under the Prescription for Health program which was announced on May 24, 2011]**
- **Should we direct physicians to contact MSP directly if they have billing questions?**

Q. Are ~~Why are you making the~~ NRTs available to minors?

- We recognize that youth can become addicted to tobacco and the BC Smoking Cessation Program hopes to provide early assistance to prevent a lifetime of smoking and related complications.
- While it is illegal to sell cigarettes and tobacco products to minors, the reality is that youth smoke and become addicted to tobacco.

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QUESTIONS AND ANSWERS

- For the non-prescription NRT products, youth can currently purchase these products from a store (not necessarily a pharmacy) without any additional support.
- However, the Smoking Cessation Program will provide youth with more information and tools should they choose to access coverage for NRTs. When a youth – under the age of 18 – calls HealthLink BC, we will request additional enrolment with QuitNow Services or consultation with a doctor.
- For the prescription drugs, all youth will be assessed by their doctor in deciding whether bupropion or varenicline is the right treatment choice instead of a NRT product.

Q. What stakholders did you consult to develop the program? ~~You committed to consulting with eight groups, did this happen?~~

-
- ~~Yes, w~~We formally consulted with all groups noted in the Premier's announcement: LIST THEM OUT
- At all of the stakeholder consultations, the Ministry ~~and~~ received a lot of positive feedback and suggestions that were considered as the program was developed. In addition to the above groups, we also consulted additional groups and quit experts in the health care system (within and outside of government), to ensure we had a broad number of perspectives to inform the program.
- Additional groups and individuals included:
    - Dr. Milan Khara, physician specializing in higher need populations in Vancouver Coastal Health;
    - Dr. Debbie Thompson, pharmacist with expertise in smoking cessation in Fraser Health;
    - Dr. Carol-Ann Saari, physician and clinical head of program at Children's and Women's Health Centre of BC in youth mental health and addictions disorders;
    - Dr. Shimi Kang, physician and researcher specializing in youth smoking cessation at Children's and Women's Health Centre of BC
    - Dr. Peter Selby, clinical director of the Addictions Program and Head of the Nicotine Dependence Clinic at the Centre for Addiction and Mental Health in Toronto

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QUESTIONS AND ANSWERS

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Grieve, Katie HLTH:EX

From: Lun, Eric HLTH:EX
Sent: December-13-10 10:04 PM
To: Chong, Elaine HLTH:EX; Chan, Dennis HLTH:EX; Fazlagic, Tijana HLTH:EX; Mochrie, Paul HLTH:EX
Subject: Re: Pfizer Meeting

For varenicline, I had asked Chris to provide an e-copy of the material if he can as it makes it easier for us and in fact is now a requirement for submissions to PSD.
Tijana - based on this, I think we can consider as resub and close the other one off. Perhaps you can contact him to thank him for the info and request an e-copy and also let him know that we'll consider the submission as resub to kick start the process again.

Eric

Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
Pharmaceutical Services Division, BC Ministry of Health Services

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From: Chong, Elaine HLTH:EX
Sent: Monday, December 13, 2010 04:43 PM
To: Chan, Dennis HLTH:EX; Lun, Eric HLTH:EX; Fazlagic, Tijana HLTH:EX; Mochrie, Paul HLTH:EX
Subject: Re: Pfizer Meeting

Dennis,

We should chat about varenicline - how about later this week or next? Now that the 2010 drug listings are behind us (soon), perhaps we can put our brains together re: smoking cessation? Feel free to propose a time - I would suggest us on this email as well as any others you might want to invite.

EC

From: Chan, Dennis HLTH:EX
Sent: Monday, December 13, 2010 01:59 PM
To: Lun, Eric HLTH:EX; Fazlagic, Tijana HLTH:EX; Chong, Elaine HLTH:EX; Mochrie, Paul HLTH:EX
Subject: Pfizer Meeting

Hi Folks,

Chris Smith of Pfizer came in on Friday to discuss a variety of things. I suspect that most of the items he raised were already discussed in your recent meeting with him and Bob Dawson, but for some reason, he seemed inclined to touch upon each file again with me.

Here are a few noteworthy points on outstanding submissions:

1) He dropped off three binders with info on varenicline (Champix) that he felt would respond to Eric's request for more info. Sarah will be dropping these off for each of you. Chris wants to set up a 2-3 hr meeting in January with us all to discuss Champix with him and several of his colleagues that would fly in for what he calls a "deep dive" to learn what BC needs before Champix can be listed

Please advise if this meeting is of interest or if you'd prefer a different response.

Not Responsive

If you anyone has any questions on the above, please do let me know.

Thanks,

Dennis

Grieve, Katie HLTH:EX

From: Weston, Megan D HLTH:EX
Sent: July-19-11 10:02 AM
To: Chong, Elaine HLTH:EX; Galbraith, Susan HLTH:EX; Fazlagic, Tijana HLTH:EX; Hardy, Jillian HLTH:EX; Margawang, Edmond HLTH:EX
Cc: Arenson, Darlene H HLTH:EX; Capelli, John HLTH:EX; Abbott, Greg W HLTH:EX
Subject: RE: Setting Quantity Limits on Smoking Cessation Claims

Bupropion at usual dose (150mg daily for 3 days, then 150mg twice daily) is 165 tablets for 12 weeks (or 171 for 12 weeks plus 3 days depending on how the prescriber writes the script and how we feel about it)

Varenicline 0.5mg dose: (0.5mg daily for 3 days, then 0.5mg twice daily) is 165 tablets for 12 weeks (or 171 for 12 weeks plus 3 days depending on how the prescriber writes the script and how we feel about it) (DIN: 2291177)

Varenicline 1mg dose: (0.5mg daily for 3 days, then 0.5mg twice daily for 4 days, then 1mg twice daily for 11 more weeks)

This one might get complicated. The starter pack (DIN 2298309) is a two week supply containing both 0.5mg and 1mg tablets and has a quantity of 25 (11 x 0.5mg tabs + 14 x 1mg tabs). The 1mg compliance pack (DIN 2291185) is a 2 week supply also, 5 packs to be dispensed for the remainder of the course (140 tablets).
The 0.5mg tablets are available in a stock bottle or within the starter pack. A pharmacy may decide to only stock the bottle rather than the starter pack. If we set a limit on the 1mg tablets to be 140, then when the stock bottle is used for the 0.5mg tablets (11 tabs dispensed), 154 of the 1mg tablets will be needed. This scenario may rarely happen because this would mean breaking a 2 week compliance pack to dispense 11 weeks of the 1mg tablets, so it might be moot, but I wanted it brought up.

NRT: patches are easy as long as the dose is regular = 84 patches

Gum: TBD as I have a meeting right this minute.

See you in an hour

Megan Weston

Pharmacist Consultant
Special Authorizations
Pharmaceutical Services, Drug Intelligence
Ministry of Health

2-2, 1515 Blanshard St
Victoria BC V8W 3C8

Phone: 250 952-2883
Fax: 250 952-1066

From: Chong, Elaine HLTH:EX
Sent: Tuesday, July 19, 2011 8:28 AM
To: Weston, Megan D HLTH:EX; Galbraith, Susan HLTH:EX; Fazlagic, Tijana HLTH:EX; Hardy, Jillian HLTH:EX;

Margawang, Edmond HLTH:EX
Cc: Arenson, Darlene H HLTH:EX; Capelli, John HLTH:EX; Abbott, Greg W HLTH:EX
Subject: RE: Setting Quantity Limits on Smoking Cessation Claims

Hi all,

Hoping we can discuss this later today at our 11am meeting.

Thanks,
EC

From: Chong, Elaine HLTH:EX
Sent: Fri, July 15, 2011 11:40 AM
To: Arenson, Darlene H HLTH:EX; Weston, Megan D HLTH:EX; Galbraith, Susan HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Hardy, Jillian HLTH:EX; Margawang, Edmond HLTH:EX
Subject: FW: Setting Quantity Limits on Smoking Cessation Claims

All,

With the prescription drugs, is there a set dose with no dose creep? If so, would one of you please calculate the quantity limit? Should we set this?

With the NRTs, we can also set a quantity limit … should we?

EC

From: Dean Billings [mailto:Dean.Billings@maximusbc.ca]
Sent: Friday, July 15, 2011 10:40 AM
To: Chong, Elaine HLTH:EX; Abbott, Greg W HLTH:EX; Capelli, John HLTH:EX
Subject: RE: Setting Quantity Limits on Smoking Cessation Claims

Hi there,

Yes, a quantity limit can be set for each DIN.

Dean Billings
Business Systems Analyst\Project Manager | Health Insurance BC | MAXIMUS Canada | Mobile: (250) 884-9591
dean.billings@maximusbc.ca

From: Chong, Elaine HLTH:EX [mailto:Elaine.Chong@gov.bc.ca]
Sent: July 15, 2011 10:04 AM
To: Abbott, Greg W HLTH:EX; Dean Billings; Capelli, John HLTH:EX
Subject: RE: Setting Quantity Limits on Smoking Cessation Claims

Thanks for this idea Greg – I think we had explored before, but it wasn't possible. Perhaps worth looking at again as this would make a lot of things easier.

EC

From: Abbott, Greg W HLTH:EX
Sent: Fri, July 15, 2011 10:02 AM

To: 'Dean Billings'; Chong, Elaine HLTH:EX; Capelli, John HLTH:EX
Subject: Setting Quantity Limits on Smoking Cessation Claims

If Dean can confirm that we can use the QTY_LIMIT field in the PharmaNet DRUGPRICE table to provide an upper limit on the amount of drug that should be dispensed at any one time to an individual, we can discuss applying that functionality as a control over smoking cessation claims. Since we are going with products with an indication specific to smoking cessation, we could set quantity limits that allow for the expected maximum dosage for that indication but do not permit quantities in excess of it.

Greg Abbott, Senior Policy Analyst - Policy, Outcomes, Evaluation and Research
Pharmaceutical Services, Ministry of Health Phone: (250) 952-2789 Fax: (250) 952-2790

Grieve, Katie HLTH:EX

From: Capelli, John HLTH:EX
Sent: July-29-11 10:05 AM
To: Chong, Elaine HLTH:EX; Fazlagic, Tijana HLTH:EX
Cc: Gobis Ogle, Barbara HLTH:EX
Subject: RE: Smoking cessation - varenicline and bupropion in Ontario

Hi Elaine,

Not Responsive

John Capelli

Manager, Policy
Policy, Outcomes Evaluation & Research
Pharmaceutical Services
B.C. Ministry of Health
Phone: (250) 952-1708

From: Chong, Elaine HLTH:EX
Sent: Friday, July 29, 2011 9:23 AM
To: Capelli, John HLTH:EX; Fazlagic, Tijana HLTH:EX
Cc: Gobis Ogle, Barbara HLTH:EX
Subject: Smoking cessation - varenicline and bupropion in Ontario

Hi John and Tijana,

Hope your Friday is going well. As I mentioned, Ontario will be covering varenicline and bupropion in Ontario, as of Aug 4. Ontario will not be covering NRTs.

I also heard that Ontario pharmacists may have an expanded scope of practice to include "prescribing" of varenicline and bupropion (expanded scope will likely happen in the fall). Could you please try to find out more details? Do you think this will be possible for BC (maybe not immediately for Sept 30, but as part of Phase 2)?

EC

Grieve, Katie HLTH:EX

From: Hardy, Jillian HLTH:EX
Sent: September-23-11 12:29 PM
To: Fazlagic, Tijana HLTH:EX
Subject: Smoking Cessation BN, Manufacturer Letters & DBR
Attachments: Smoking Cessation. 897551.BN.docx; 2481_Nicorette and Nicoderm (nicotine replacement therapy). ltr.docx; 1650 Champix (varenicline). ltr.docx; 2481.NICORETTE and NICODERM (nicotine replacement therapy).DBR.docx

Hi Tijana,

I have attached the smoking cessation DBN, manufacturer letters and DBR for your review. It seemed like a lot of information was needed for the DBN and it is longer than 2 pages, however I though you could delete some of the information that you didn't think was necessary.

As both Sherrill and Katie are away, I was not able to assign a CLIFF number to the varenicline manufacturer letter – I will do so on Monday and also confirm the contacts from Pfizer and McNeil.

The attached documents are also saved in the usual place on the LAN.

Thanks,
Jill

Jillian Hardy
Pharmacist Consultant, Formulary Management
Pharmaceutical Services Division
British Columbia Ministry of Health
(250) 952-1840
Jillian.Hardy@gov.bc.ca

Grieve, Katie HLTH:EX

From: Phillips, Vivienne HLTH:EX
Sent: March-25-11 2:33 PM
To: Fazlagic, Tijana HLTH:EX
Cc: Vetter, Daniel HLTH:EX; Hardy, Jillian HLTH:EX; Margawang, Edmond HLTH:EX; Hodges-Whittaker, Diane HLTH:EX
Subject: Updated - Manufacturer Reports for Smoking Cessation
Attachments: Manufacturer Comments Clinical Practice Reports Pfizer.pdf; Manufacturer Comments Clinical Practice Report Valeant Canada.pdf

Hi Tijana,

I have now pfd'd the reports and these are the reports to be used for DBC.

Thank you,

Viv

From: Phillips, Vivienne HLTH:EX
Sent: Friday, March 25, 2011 2:11 PM
To: Fazlagic, Tijana HLTH:EX
Cc: Vetter, Daniel HLTH:EX; Hardy, Jillian HLTH:EX; Margawang, Edmond HLTH:EX; Hodges-Whittaker, Diane HLTH:EX
Subject: RE: Manufacturer Reports for Smoking Cessation

Hi Tijana,

Your welcome!

Yes, that is where I have saved the Manufacturer Reports - Drugs-CDR/ Smoking Cessation folder.
Cheers,

Viv

From: Fazlagic, Tijana HLTH:EX
Sent: Friday, March 25, 2011 2:07 PM
To: Phillips, Vivienne HLTH:EX
Cc: Vetter, Daniel HLTH:EX; Hardy, Jillian HLTH:EX; Margawang, Edmond HLTH:EX; Hodges-Whittaker, Diane HLTH:EX
Subject: FW: Manufacturer Reports for Smoking Cessation

Hi Viv,

Thanks for forwarding these to me.

Are these documents saved in Drugs-CDR/ Smoking Cessation folder?

Jill,
Please make sure a copy is included in the DBC folder and it shows up in the list of documents on the agenda.

Thank you,
Tijana

Tijana Fazlagic , B.Sc.(Pharm), MSc
Director
Formulary Management
Pharmaceutical Services
(250) 952-1475
Tijana.Fazlagic@gov.bc.ca

From: Phillips, Vivienne HLTH:EX
Sent: Friday, March 25, 2011 1:42 PM
To: Fazlagic, Tijana HLTH:EX
Subject: Manufacturer Reports for Smoking Cessation

Hi Tijana,

As promised the Manufacturer Reports for Smoking Cessation.

Cheers,

Viv