

# Post-market review of medicines for smoking cessation: stakeholder forum summary

The stakeholder forum was held as a webinar at 11am AEDT on 3 December 2020. It consisted of presentations from the department and reference group, 11 multiple choice questions that participants answered in a live poll, a live question and answer session, and a survey that participants responded to after the forum.

Of 41 participants attending the forum, 8 were associated with the department or the review reference group, and 33 were external participants.

This document is intended to provide a broad summary of the views expressed by stakeholders and only information provided at the forum or through survey questions has been included. No attempt was made to reach consensus.

## Key points from the forum

Of the 33 external participants attending the forum, approximately one third worked for a sponsor medicine company or an organisation representing the pharmaceutical industry. No participants identified as consumers or Aboriginal and Torres Strait Islander health workers.

Forum participants considered that the Pharmaceutical Benefits Scheme (PBS) restrictions for accessing smoking cessation medicines could be improved by allowing:

- combination therapy
- longer duration of nicotine replacement therapy (NRT)
- multiple courses per year
- higher doses (increased quantities) of NRT.

Participants also considered it preferable to tailor treatment to the individual.

Common causes of treatment failures were identified as:

- under dosing (dose and/or duration) of NRT
- insufficient management, follow-up and support
- access issues, especially for people in rural and remote areas
- high cost of smoking cessation therapy.

## Purpose and context

The aim of the Stakeholder Forum was to ensure that the report of the Pharmaceutical Benefits Scheme (PBS) post-market review of medicines for smoking cessation includes the views of a wide range of stakeholders, and that these views inform the discussions about future options for the Pharmaceutical Benefits Advisory Committee (PBAC) to consider. The PBAC is an independent, expert committee that makes recommendations to the government on the subsidy of medicines on the PBS. This summary of stakeholder input received at the forum will be included in the review's report to the PBAC.

Consumers, clinicians and peak bodies who have an interest in smoking cessation, and pharmaceutical sponsors who have a current PBS medicine listing for a smoking cessation therapy, were invited to participate in the forum.

The review is being conducted under the Australian Government's Post-market Review Program for PBS-listed medicines. A reference group has been established to provide independent expert advice to the review, and includes clinicians, technical experts, consumers and industry representation.

## **Department presentations**

The department explained the aim of post-market reviews, how they are initiated and how they are conducted (including consultation and the role of the reference group).

The department explained the reasons for this post-market review of medicines for smoking cessation in the context of current clinical guidelines, a best-practice approach and equity considerations.

A presentation was made by the Chair of the reference group for the PMR of medicines for smoking cessation. Participants were informed of the medicines included in the review (and those that are out of scope), the review's terms of reference and next steps following the stakeholder forum.

The slides for these presentations are available on the [Public Consultation page for the Post-market Review of medicines for smoking cessation](#).

## Responses to poll questions

Respondents answered the following questions in a live poll during the forum. Respondents were able to choose multiple answers to each question.

1. Are you a:

- Consumer/patient (0 votes)
- General Practitioner (2 votes)
- Nurse (1 vote)
- Aboriginal and Torres Strait Islander Health worker (0 votes)
- Pharmacist (8 votes)
- Other Health Professional (1 vote)
- Work for an organisation supporting people to quit smoking (4 votes)
- Work for an organisation supporting consumers with a chronic illness (1 vote)
- Work for an organisation representing health professionals (4 votes)
- Work for a Sponsor medicine company or an organisation representing the pharmaceutical industry (11 votes)

Total number of votes = 32

Around one-third of respondents worked for a sponsor medicine company or an organisation representing the pharmaceutical industry. No respondents identified as consumers/patients or Aboriginal and Torres Strait Islander health workers.

2. Have you used any of the following smoking cessation medicines?

- Champix (Varenicline) (1 vote)
- Zyban (Bupropion) (1 vote)
- Nicotine Replacement Therapy monotherapy – Patches (Any brand) (1 vote)
- Nicotine Replacement Therapy monotherapy – Gum or lozenge (Any brand) (1 vote)
- Nicotine Replacement Therapy monotherapy – Other (Any brand) (2 votes)
- Nicotine Replacement Therapy combination therapy – Patches AND Gum/lozenge/other in the same course of treatment (3 votes)
- Other combination therapy (1 vote)
- Counselling support only (1 vote)
- Other (0 votes)
- Not applicable (19 votes)

Total number of votes = 30

Of those who used smoking cessation therapy, NRT combination therapy was the most commonly used. The vast majority of respondents answered this question as 'not applicable'.

3. How have you accessed smoking cessation medicines?

- PBS-subsidised script (2 votes)
- Private script (1 vote)
- Remote Area Access Scheme (0 votes)
- Over the counter at a pharmacy (3 votes)
- Other retail such as the supermarket (1 vote)
- Not applicable (15 votes)

Total number of votes = 22

Of those who accessed smoking cessation medicines, the majority accessed these medicines over the counter at a pharmacy, followed by through PBS subsidised script. The vast majority of respondents answered this question as 'not applicable'.

4. Have you ever used one PBS-subsidised smoking cessation medicine in conjunction with a formulation obtained over the counter? For example, varenicline (Champix) supplied on script and nicotine patches bought over the counter, or nicotine patches supplied on script with nicotine gum/lozenges bought over the counter?

- Yes (8 votes)
- No (3 votes)
- Not applicable (18 votes)

Total number of votes = 29

Of those who had used smoking cessation therapies, the majority had used a formulation obtained over the counter in conjunction with a PBS-subsidised smoking cessation medicine. The vast majority of respondents answered this question as 'not applicable'.

5. Have you used smoking cessation therapies for reasons other than to quit (ie cut down on number of cigarettes)?

- Yes (9 votes)
- No (0 votes)
- Not applicable (20 votes)

Total number of votes = 29

Of respondents who had used smoking cessation therapies, all had used them for reasons other than to quit (for example to cut down the number of cigarettes). The vast majority of respondents answered this question as 'not applicable'.

6. Have you experienced side effects from using smoking cessation therapy and, if so, did it cause you to stop your treatment? If yes, please provide further information via the survey after the presentation.

- Yes – the side effects caused me to stop taking the smoking cessation medicine (3 votes)
- Yes – the side effects did not cause me to stop taking the smoking cessation medicine (0 votes)
- No (3 votes)
- Not applicable (21 votes)

Total number of votes = 27

Of those who had used smoking cessation therapies, half had not experienced side effects and half experienced side effects that caused them to stop taking the medication. The vast majority of respondents answered this question as 'not applicable'.

7. Have you been unable to purchase a prescribed or recommended smoking cessation therapy due to their cost?

- Yes (7 votes)
- No (0 votes)
- Not applicable (20 votes)

Total number of votes = 27

Of those who had purchased smoking cessation therapies, all had been unable to purchase a therapy due to cost. The vast majority of respondents answered this question as 'not applicable'.

8. Have you experienced other barriers to access smoking cessation therapies? If yes, please provide further information via the survey after the presentation.

- Yes (4 votes)
- No (1 vote)
- Not applicable (22 votes)

Total number of votes = 27

More respondents had experienced barriers to accessing smoking cessation therapies than not. The vast majority of respondents answered this question as 'not applicable'.

9. Who recommended/prescribed the smoking cessation medicines you used?

- General Practitioner (1 vote)
- Nurse (0 votes)
- Aboriginal and Torres Strait Islander health worker (0 votes)
- Pharmacist (2 votes)
- Other health professional (0 votes)
- Smoking cessation organisation (such as Quitline) (0 votes)
- Other consumer/friend/family (0 votes)
- Not applicable (25 votes)

Total number of votes = 28

Pharmacists or General Practitioners were the only health professionals to have recommended or prescribed smoking cessation medicines to the respondents. The vast majority of respondents answered this question as 'not applicable'.

10. For Health professionals – Have you prescribed or recommended the following medicines for smoking cessation?

- Champix (Varenicline) (6 votes)
- Zyban (Bupropion) (4 votes)
- Nicotine Replacement Therapy monotherapy – Patches (Any brand) (7 votes)
- Nicotine Replacement Therapy monotherapy – Gum or lozenge (Any brand) (7 votes)
- Nicotine Replacement Therapy monotherapy – Other (Any brand) (7 votes)
- Nicotine Replacement Therapy combination therapy – Patches AND Gum/lozenge/other in the same course of treatment (8 votes)
- Counselling support only (3 votes)
- Other (2 votes)
- Not applicable (7 votes)

Total number of votes = 51

Respondents had most commonly prescribed or recommended NRT combination therapy, followed by various types of NRT monotherapy.

11. For Health professionals – What is your preferred smoking cessation therapy to prescribe/recommend?

- Champix (Varenicline) (7 votes)
- Zyban (Bupropion) (1 vote)
- Nicotine Replacement Therapy monotherapy – Patches (Any brand) (3 votes)
- Nicotine Replacement Therapy monotherapy – Gum or lozenge (Any brand) (3 votes)
- Nicotine Replacement Therapy monotherapy – Other (Any brand) (3 votes)
- Nicotine Replacement Therapy combination therapy – Patches AND Gum/lozenge/other in the same course of treatment (11 votes)
- Other combination therapy (4 votes)
- Counselling support only (1 vote)
- Based on individual (11 votes)
- Not applicable (9 votes)

Total number of votes = 53

Most respondents preferred to recommend NRT combination therapy, and the same number of respondents indicated that therapy would be based on the individual.

## Question and answer session

Forum participants submitted the following questions during the question and answer session which were answered by the Department of Health or members of the review reference group.

**Q:** Will the PBS allow access to combination therapy (eg varenicline or patches, plus a fast-acting product such as gum or lozenges) and higher quantities of therapies, and will the duration of therapy be extended?

**A:** Expert clinical advisers have noted these issues as being of concern. The post-market review is considering the evidence relating to combination therapy, dose and duration of therapy, as part of this review.

**Q:** Are nicotine inhalers and mouth spray within the scope of the review?

**A:** Inhalers and mouth spray are not listed on the PBS and so are outside the review's scope because sponsors have not yet made a submission for PBS-listing these products.

**Q:** Is the review considering mechanisms to strongly emphasise behavioural interventions such as Quitline?

**A:** The current PBS restrictions state that medicines should be prescribed in the context of behavioural interventions. The reference group has noted that some models exist that deliver therapies through referral to Quitline, as well as other types of approaches. The review will consider the potential to strengthen the role of behavioural interventions.

**Q:** Is it possible to automatically include a call from Quitline for people who receive a prescription for smoking cessation medicines?

**A:** Current mechanisms relating to Quitline require the individual to give consent, but this suggestion could be considered.

**Q:** How can we provide evidence to the review regarding combination therapies?

**A:** The sponsor should include all relevant evidence in their submission to the PBAC, including studies that demonstrate clinical outcomes. Any evidence submitted to this review needs to be presented in a way the committee can evaluate it in terms of comparative clinical effectiveness and cost-effectiveness.

**Q:** Nicotine dependence is a chronic relapsing condition. Will the review consider the current limitations for one course per calendar year?

**A:** Yes, the review will consider the evidence relating to multiple courses per year.

The following questions were received after the forum had closed. These questions are answered by the Department of Health.

**Q:** Would the PBAC consider unpublished evidence from clinician experience?

**A:** The PBAC will consider all stakeholder input provided for the post-market review of medicines for smoking cessation. This information helps the committee understand what consumers consider to be the main benefits and harms of the proposed medicine or vaccine. These may be different to those measured in the clinical trial evidence presented. There will be a further opportunity for stakeholder consultation once the draft post-market review report is available for comment.

**Q:** Is the cost-effectiveness also reviewing whether the current subsidisation is actually cost-effective? Could argue it's possibly not, due to underdosing/subtherapeutic.

**A:** Your comment will be passed on to the Review Reference Group. An economic analysis may be conducted under Term of Reference 4 of the post-market review of medicines for smoking cessation, if recommended by the PBAC following the findings for Terms of Reference 1, 2 and 3. Revised or new economic modelling may be required if there is new evidence available that would change previous assumptions used to model cost-effectiveness.

**Q:** Would the Department consider a waiver for fees a sponsor has to pay for a smoking cessation therapy to be included on the PBS?

**A:** The *National Health Act 1953* provides authority for the cost recovery of Australian Government-funded services from applicants seeking new, or changes to existing, listings of medicines, vaccines and other products or services on the PBS or the NIP. The requirements of cost recovery are prescribed by the [National Health \(Pharmaceuticals and Vaccines – Cost Recovery\) Regulations 2009](#) (the Regulations).

An applicant may apply to the delegate of the Secretary to waive the fee for ATAGI pre-submission advice, submission services, a pricing services or list management services if the application involves a public interest component and where payment of the fee would make proceeding with the application financially unviable.

More detailed information on fee waivers is available on our webpage at [PBS Cost Recovery fees and charges](#). Please scroll further down the page to view specific information on fee waivers.

More general information on PBS cost recovery and other useful resources are available on the [PBS Cost Recovery](#) webpage, including the [Cost Recovery Administrative Guidelines for Applicants](#) which may be helpful for further guidance on fee waivers.

If you have any further queries please contact the PBS Cost Recovery Unit at [pbscostrecovery@health.gov.au](mailto:pbscostrecovery@health.gov.au).



## Responses to survey questions

Participants were given the option to provide responses to survey questions either before or after the stakeholder forum.

There were 14 responses to the survey. Not all respondents completed all questions.

### **1. What aspects of the current PBS restrictions could be improved to promote quality use of medicines for smoking cessation?**

A total of 13 responses were received to this question. Responses were categorised into the following themes, listed by frequency of response.

#### ***Allow combination therapy (11 respondents)***

Respondents noted that combination therapy (such as nicotine patches plus fast-acting oral NRT, or varenicline plus NRT) is best practice and supported by current clinical guidelines. The risk of relapse is higher if NRT is insufficient, and tailoring therapy to the individual can maximise the chance of a successful quit attempt. The cost of over-the-counter NRT can be a significant barrier for many people, particularly those from populations with higher rates of smoking such as lower socioeconomic groups, Aboriginal and Torres Strait Islander people, and people with a mental illness.

#### ***Allow longer duration/multiple courses per year of NRT (11 respondents)***

Respondents felt that longer duration of NRT supports successful quit attempts, because nicotine dependency is a chronic relapsing disease. The current restriction allowing one 12-week course of NRT per calendar year for non-Indigenous patients may be insufficient, and is a significant barrier to successful quit attempts.

#### ***Allow higher doses/increased quantities (6 respondents)***

Respondents felt that higher doses and larger quantities of NRT should be permitted (such as 21 mg patches plus 4 mg oral NRT, or multiple patches). Insufficient doses of NRT are a key contributor to unsuccessful quit attempts (see responses to survey question 3).

#### ***Include all formulations (4 respondents)***

Respondents felt that all forms of NRT should be subsidised under the PBS because various formulations may not be clinically appropriate for certain patients. This includes nicotine inhalers and mouth spray.

#### ***Align with guidelines/evidence (3 respondents)***

Respondents felt that the PBS restrictions should align with current clinical guidelines (such as the RACGP guidelines), published research evidence and best practice. This includes encouraging combination therapy, and behavioural counselling and support.

#### ***Combine with counselling/behavioural interventions (3 respondents)***

Respondents felt that mechanisms to increase the uptake of behavioural interventions and counselling with smoking cessation medicines were warranted, and that the need to combine cessation medicines with counselling could be included in the PBS restriction as a criterion for subsidy for all populations. The PBS restrictions for Aboriginal and Torres Strait Islander people recommend comprehensive support and counselling, but it is not a requirement. Evidence and best practice identify the importance of multisession behavioural interventions to support people to quit.

One respondent noted that government-funded smoking cessation programs (such as Quitline) are limited in the community, and that investing in government-funded face-to-face programs or subsidising support through established psychology or counselling services could be considered.

***Allow use for cutting down, not just quitting (2 respondents)***

Respondents considered that cutting down is a method of quitting.

***Other (2 respondents)***

One respondent suggested individualising treatment options by phone authority. One respondent suggested removing the requirement for 'readiness to cease smoking' because evidence supports clinicians providing an 'offer of support' regardless of the person's intention to quit, and that support can be a key driver in successful quit attempts.

***No improvements required (1 respondent)***

One respondent indicated that there were no issues with the current PBS restrictions.

**2. What patient relevant outcomes from the use of medicines for smoking cessation are important?**

A total of 9 responses were received to this question. Responses were categorised into the following themes, listed by frequency of response:

- quality of life (6 respondents), including physical and mental wellbeing, social and community connectedness (attaining secure housing or employment) and improving personal relationships
- cessation (5 respondents)
- safety/adverse effects (5 respondents), including minimal side effects, and potential for abuse or misuse
- acceptability of therapy (4 respondents), including personal experience of, and satisfaction with, using the therapy
- reduction in smoking (4 respondents), although respondents noted that cutting down confers little or no health benefits, but may have financial or social benefits and can be considered a step towards cessation
- quit attempt (3 respondents), acknowledging the positive impact this may have on subsequent attempts and eventual cessation
- other (3 respondents), including short and long-term health benefits, duration of therapy (some people may need long-term therapy) and the need to consider both quantitative and qualitative measures
- quit duration (2 respondents), including length of quit attempt and duration of abstinence
- medical outcomes (2 respondents), including reduced length of hospital stay, reduction in hospital admissions/readmissions, symptom control, improved treatment outcomes (including post-surgical, chemotherapy outcomes)
- reduce cravings (1 respondent)
- cost (1 respondent), smoking rates are higher in populations considered to be both socially and economically disadvantaged. This cohort generally has poor social networks, lower health literacy and access to health care and relative lack of opportunity. Although smoking

cessation therapies are considered the 'cheaper alternative' to the rising cost of cigarettes, the initial outlay (for non-PBS subsidised medicines) is substantial for people with low incomes (on Disability Support Pensions, for example). These costs are a significant barrier for many people to try quitting or repeat a quit attempt. Additionally, many people attempting to quit will continue to access tobacco products as well as smoking cessation therapies as they overcome and manage their dependency with support, which places financial strain on the individual and their family.

### **3. What are the most common causes of treatment failures (i.e. stopping using the medicines or unsuccessful in quit attempt) with respect to medicines for smoking cessation?**

A total of 11 responses were received to this question. Responses were categorised into the following themes, listed by frequency of response.

#### ***Underdosing (dose and/or duration) (8 respondents)***

Respondents felt that inadequate dose and duration of NRT often leads to relapse. This can include using lower strength patches, restricting the duration of usage, stepping down therapy too early, or not using combination therapies to optimise treatment.

#### ***Insufficient management/follow up/support (5 respondents)***

Respondents felt that counselling and other support services are important to support people attempting to quit. This includes proactive referral from health professionals to evidence-based counselling or behavioural interventions, and providing a range of options for people to access (e.g. face to face, text based, mobile apps, web based).

#### ***Access issues (4 respondents)***

Respondents noted that lack of access to smoking cessation medicines is particularly important for people in regional and remote areas.

#### ***Adverse effects (3 respondents)***

No additional comments were made.

#### ***High cost of cessation therapy (3 respondents)***

Respondents considered that financial cost was an important factor, particularly for non-PBS subsidised therapies.

#### ***Incorrect use (3 respondents)***

Respondents felt that clear instructions for use are required, including improving Consumer Medicines Information and providing education for health professionals.

#### ***Lack of medicines knowledge (3 respondents)***

Respondents felt there were misconceptions among consumers and health professionals regarding the safety and efficacy of smoking cessation medicines (including expectations of effectiveness and concerns about addictiveness), as well as a lack of education on how to use the product effectively.

#### ***Lack of tailored intervention (2 respondents)***

Respondents felt that it was essential to tailor treatment to the individual, which requires having a range of options available.

### ***Poor compliance/adherence (2 respondents)***

No additional comments were made.

### ***Other (2 respondents)***

One respondent noted limited use of oral fast-acting NRT in combination with varenicline. The other respondent noted that some people may not feel that bupropion and varenicline alleviate cravings.

## **4. What resources can people access for support in using smoking cessation therapies?**

A total of 11 responses were received to this question. Respondents listed the following resources:

- Consumer Medicines Information – respondents suggested that these need to be updated to align with current best practice
- information from sponsors
- Quitline
- information from government or peak bodies (written or online)
- clinician support (GP, pharmacist, tobacco treatment specialist, alcohol and drug services) – respondents considered that education and upskilling is required
- behavioural support/counselling
- My Quit Buddy app
- advertisements and media.

## **5. What are the challenges to capturing the health benefits in clinical trials of these medicines and how representative of the broader smoking population are the participants?**

A total of 9 responses were received to this question.

Respondents noted several issues with study populations. Some felt that priority populations (such as people with mental illness and pregnant women) are usually excluded from studies, which may bias results in favour of the cessation medicine. Other respondents felt that study participants were more likely to be heavier smokers or have higher nicotine dependency. Study participants may not represent the broader community of smokers in terms of health literacy and willingness to engage in treatment, and the monitoring and follow-up built into the trial may serve as motivation.

Respondents noted that health benefits are not usually a primary or secondary outcome that is measured in clinical studies, and studies focus on quit attempts. Respondents noted that the time frame for follow-up does not allow long-term monitoring of abstinence or subsequent relapse treatment, and does not allow long-term health benefits (such as cardiovascular benefits) to be captured. Respondents also noted the difficulty in attributing health benefits to cessation alone.

## **6. Please provide detail on how smoking cessation therapies are being used with respect to length of treatment, dose and frequency of use? Including smoking cessation therapies bought over the counter or on private scripts.**

A total of 9 responses were received to this question, including the following comments.

Some clinical guidelines support the use of combination therapy (nicotine patch and faster-acting NRT) and higher doses (4 mg lozenge/gum with patch and multiple patches) for longer durations. All

formulations of NRT are recommended. Varenicline is also considered, particularly within the outpatient setting.

Therapies are being used for longer than indicated, to allow people additional time to abstain, and often in combination (short + long acting NRT combination, varenicline + NRT) to manage withdrawal and cravings.

People who are highly nicotine dependent are under-dosed with NRT. There is good evidence that combining varenicline and NRT is very effective, and that longer treatment for both is better than short treatment. Smokers range in their ability to metabolise nicotine and this has a great bearing on their need for NRT. Therefore, it is important to obtain details of the smoker's history and past experiences with pharmacotherapies to tailor the treatment to the individual.

Statewide clinical guidelines (such as those developed by Quit and Alfred Health at [quit.org.au/healthservices](http://quit.org.au/healthservices)) provide the gold standard with regard to treatment, dose and frequency.

Queensland Health Smoking Cessation Clinical Pathway has adapted the Bittoun algorithm for NRT dose adjustment and this has been used in current practice since 2012. This algorithm was peer reviewed and has been approved by the Queensland Statewide Respiratory Clinical Network.

Carbon monoxide monitoring is a tool that is underused by general practitioners (GPs) for treatment of nicotine dependence. More education is required for GPs to use this as a tool to promote smoking cessation. Carbon monoxide monitoring can be used for assisting with dose adjustment of NRT or when combining therapies.

Evidence exists for using high-dose treatments over low-dose patches for initiation of therapy. Low dose patches should be reserved for weaning NRT if needed.

Cahill et al showed evidence for combination NRT being similar to varenicline and more effective than other treatments. Nortriptyline is also another option listed in current Royal Australian College of General Practitioners (RACGP) guidelines, but a knowledge gap exists in the GP community for its use for smoking cessation. Nortriptyline is beneficial when other options are not suitable due to their side effects.

Some people require longer treatment than the prescription allows, others cease too soon (often due to relapse or resulting in a greater chance of relapse).

Often people require more than 3 months treatment, repeated courses and a combination of Champix and NRT in hard-to-treat patients.

Some hospital formularies carry both patch and inhaler for patient use. However, they are not being routinely prescribed or used for patients in the respondent's experience.

One respondent described a well-established, pharmacist-led clinical guideline for the management of nicotine-dependency among patients that is based on evidence-based best practice. Combination therapies involve prescribing nicotine patches (21 mg for the majority of patients) together with oral formulations (often more than one formulation prescribed for patient use). The choice of oral formulation is based on patient preference and clinical consideration; for example, nicotine gum is not initiated for patients with active reflux or patients scheduled for a surgical procedure (day of surgery). Access to all forms of oral formulations (both PBS and non-PBS subsidised NRT) not only increase the chance of patient uptake of the offer of support to quit, but also increases compliance with smoke-free policy (supporting temporary abstinence for those not wanting to quit). This approach supports patients to use oral fast-acting NRT formulations in anticipation of a smoking trigger, not just when cravings arise – frequent and high doses of these formulations is common. This support extends to smoking cessation care via a smoking cessation team that provides bedside consultations to provide tailored support to the patient and offer ongoing support following discharge. The use of NRT can extend beyond 12 weeks and often involves the tapering of the use of

oral NRT for up to 6 months. A successful quit attempt is maximised when pharmacotherapies are coupled with behavioural intervention and a smoking cessation program.

**7. For smokers only – Please provide detail on what, if any, barriers you have encountered to accessing smoking cessation therapies?**

Although no forum participants identified as a consumer of smoking cessation products (see poll question 1), one response was received to this question, which noted that the price of NRT in pharmacies varies widely.

**8. For people attempting to quit – What has been your experience with receiving comprehensive support and counselling?**

Although no forum participants identified as consumer/patient (see poll question 1), one response was received to this question, which noted that smoking cessation clinics run in hospitals by specialist tobacco treatment specialists are highly beneficial.

**9. For prescribers only – Have you recommended non-subsidised medicines for smoking cessation? E.g. over-the-counter NRT, private scripts. If so, what proportion of patients who are attempting to quit smoking would you recommend non-PBS subsidised therapy to and why (i.e. combination use, extended treatment length, higher dose/length of treatment)?**

A total of 5 responses were received to this question. All respondents indicated that they routinely recommend non-subsidised medicines for smoking cessation. Respondents made the following comments:

Most people who smoke have a high enough level of dependence to require combination therapy.

One respondent described their clinical practice, where combination NRT is recommended to the majority of people who smoke (based on a heaviness of smoking index assessment) and oral NRT formulations are recommended for people who are currently undergoing treatment with varenicline. The recommendation of oral fast-acting NRT is the preferred choice instead of actively smoking during the initial treatment phase of varenicline (and if required to prevent a slip-up throughout the course of treatment). There is well established safety and efficacy data with regard to the use of combination therapies, and that side effects are rare and similar to monotherapy (use of a single NRT). Side effects are most often related to incorrect use or technique of the formulation and can be most often easily managed from the advice of a health professional.

**10. For prescribers only – What has been your experience with providing or recommending comprehensive support and counselling?**

A total of 5 responses were received to this question, including the following comments:

Trained clinicians and Quitline work best.

Patients are generally very receptive and appreciative when proper time is taken to provide counselling and follow-up.

Quitline is an effective, evidence-based service that, when used in conjunction with medications, give people the greatest likelihood of stopping smoking. However, its role is often not clearly understood by health professionals.

In one respondents experience as a pharmacist, consumers of smoking cessation products responded positively to re-engagement and a repeated offer of support (combination therapies

together with behavioural support). Consumers voice their frustration in the inability to achieve a successful quit attempt due to lack of subsidised smoking cessation therapies and inadequate smoking cessation support in the community. Multisession comprehensive support (motivational interviewing) has been integral to successful outcomes for smokers accessing a pharmacy led program.

When providing counselling alongside evidence-based pharmacotherapy, there have been positive results (e.g. successful cessation, often biochemically verified). There is, however, an underlying perception among both consumers and clinicians of the lack of importance of counselling to support quitting (in combination with clinically appropriate pharmacotherapy).

### **11. Please provide any other feedback about your experience with smoking cessation medicines here.**

A total of 4 responses were received to this question and included the following comments.

Ensuring the accessibility and availability of medications consistent with clinical guidelines is paramount to supporting people to quit smoking and accelerating the decline in prevalence within Australia.

Current PBS restrictions should be amended to allow combination NRT, given current evidence indicates it is as effective as varenicline and more effective than monotherapy with NRT.

Support smoking cessation based on best practice – combination therapies, longer duration, higher dosing together with behavioural support (and education on best practice approaches). The misalignment of best practice and currently subsidised smoking cessation therapies hinders both access and compliance to recommended best practice therapy among the majority of people who smoke. Relapse and failed quit attempts are also impacted by the lack of subsidised options.

One response was received from an individual who runs a specialist smoking cessation clinic for patients not fit for surgery due to being a current smoker. The clinic has been running since January 2017. The response provided the following insights:

- the majority of people required combination NRT therapy, some also required NRT plus Champix in order to achieve complete cessation;
- use of combination NRT instead of Champix meant that side effects from Champix, such as mood changes or bad dreams, were avoided;
- some side effects from smoking cessation medications need to be managed with other supportive therapy, as most are likely related to underlying anxiety;
- closer monitoring can lead to success rates as high as 80%;
- most patients take more than 3 months to achieve full cessation and a follow-up post-cessation helps prevent relapse;
- carbon monoxide monitoring is used as a good motivational tool for patients to show treatment efficacy and can be used by GPs just like blood pressure monitoring to monitor treatment effect however, GPs lack knowledge of this device; and
- the majority of patients also require dose adjustments to more than one NRT patch.

One respondent considered that NRT patches of lower than 21 mg/24 hour strength were not effective and noted that lower strength patches have never been used in their smoking cessation clinic.

Many GPs do not understand the PBS restrictions for patches and have incorrectly advised patients that NRT is not on the PBS and should be purchased over the counter. When smokers were able to access additional support from Quitline plus free NRT, success rates improved.

It is unfortunate smoking cessation specialists and tobacco treatment specialist were unaware and uninvited to present important material and evidence to this committee prior to this forum.



# Appendix 1 Forum participants

## External participants

Participant	Organisation
[REDACTED]	National Aboriginal Community Controlled Health Organisation
[REDACTED]	University of New South Wales
[REDACTED]	Heart Foundation
[REDACTED]	SA Government
[REDACTED]	Medicines Australia
[REDACTED]	GSK
[REDACTED]	Aspen Pharmacare
[REDACTED]	Pharmacy Guild of Australia
[REDACTED]	Bridging Healthcare
[REDACTED]	Thoracic Society of Australia and New Zealand
[REDACTED]	Queensland Health
[REDACTED]	Alfred Health
[REDACTED]	Queensland Health
[REDACTED]	NSW Health
[REDACTED]	Cancer Council Victoria
[REDACTED]	Perrigo
[REDACTED]	Pharmacy Guild of Australia
[REDACTED]	UNSW
[REDACTED]	Alfred Health
[REDACTED]	Society of Hospital Pharmacists of Australia
[REDACTED]	NSW Health
[REDACTED]	National Aboriginal Community Controlled Health Organisation
[REDACTED]	SA Government
[REDACTED]	Bond University
[REDACTED]	Aspen Pharmacare
[REDACTED]	Johnson and Johnson
[REDACTED]	Perrigo
[REDACTED]	University of Notre Dame
[REDACTED]	Pfizer
[REDACTED]	Pfizer
[REDACTED]	Consumer Healthcare Products Australia

██████████	Perrigo
██████████	Pfizer

### Department of Health, reference group and scribe

Participant	Organisation
██████████	Department of Health
██████████	Department of Health
██████████	Department of Health
██████████	Department of Health
██████████	Reference group
██████████	Reference group
██████████	Reference group
██████████	Biotext (scribe)

## Appendix 2 PBS restrictions<sup>1</sup>

### Summary of PBS restrictions for smoking cessation therapies

Items	Restriction
<p><b>BUPROPION</b></p> <ul style="list-style-type: none"> <li>•bupropion hydrochloride 150 mg modified release tablet, 90</li> <li>•bupropion hydrochloride 150 mg modified release tablet, 30</li> </ul>	<p><b><u>Authority Required (STREAMLINED)</u></b> Nicotine dependence</p> <p><b>Clinical criteria:</b></p> <ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have indicated they are ready to cease smoking, AND</li> <li>•Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period. AND</li> <li>•<b>Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment (90 pack).*</b></li> </ul> <p><b>Treatment criteria:</b></p> <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated. Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>•Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.</li> <li>•The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.</li> <li>•<b>A patient may only qualify for PBS-subsidised treatment under this treatment phase (30 pack) restriction once during a short-term course of treatment. *</b></li> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul> <p style="text-align: right;">*Differences between pack sizes in <b>bold</b> above</p>

<sup>1</sup> Extracted from pbs.gov.au 17 December 2020

Items	Restriction
<p><b>VARENICLINE</b></p> <ul style="list-style-type: none"> <li>•varenicline 1 mg tablet, 56 (continuation pack)</li> <li>•varenicline 500 microgram tablet [11] (&amp; varenicline 1 mg tablet [42], 53 (initiation pack)</li> </ul>	<p><b>Authority Required (STREAMLINED)</b> Nicotine dependence</p> <p><b>Clinical criteria:</b></p> <ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, AND</li> <li>•<b>Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment. * AND</b></li> <li>•<b>Patient must have indicated they are ready to cease smoking (initiation pack). AND</b></li> <li>•<b>Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period (initiation pack).</b></li> </ul> <p><b>Treatment criteria:</b></p> <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program. Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</li> <li>•Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>•A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.</li> <li>•A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment (<b>continuation pack</b>).</li> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> <li>•The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months (<b>for initiation pack</b>).</li> </ul> <p style="text-align: right;"><b>*Not required under one authority code</b></p>

<p><b>NICOTINE LOZENGE/PATCH/GUM</b></p> <ul style="list-style-type: none"> <li>•nicotine 4 mg lozenge, 216</li> <li>•nicotine 21 mg/24 hours' patch, 7*</li> <li>•nicotine 4 mg chewing gum, 216</li> <li>•nicotine 7 mg/24 hours' patch, 28</li> <li>•nicotine 25 mg/16 hours patch, 28</li> <li>•nicotine 2 mg lozenge, 216</li> <li>•nicotine 21 mg/24 hours' patch, 28</li> <li>•nicotine 2 mg chewing gum, 216</li> <li>•nicotine 14 mg/24 hours patch, 7*</li> <li>•nicotine 7 mg/24 hours patch, 7*</li> <li>•nicotine 14 mg/24 hours patch, 28</li> </ul> <p><b>*Repatriation Care Item</b></p>	<p><b><u>Restricted Benefit</u></b> Nicotine dependence</p> <p><b>LOZENGE/GUM</b> <b>General Population</b> <b>Clinical criteria:</b></p> <ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have indicated they are ready to cease smoking, AND</li> <li>•Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.</li> </ul> <p><b>Treatment criteria:</b></p> <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated. Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</li> </ul> <p><b>Aboriginal or a Torres Strait Islander person</b> <b>Population criteria:</b></p> <ul style="list-style-type: none"> <li>•Patient must be an Aboriginal or a Torres Strait Islander person.</li> </ul> <p><b>Clinical criteria:</b></p> <ul style="list-style-type: none"> <li>•The treatment must be the sole PBS-subsidised therapy for this condition.</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>•Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.</li> <li>•Benefit is improved if used in conjunction with a comprehensive support and counselling program.</li> </ul> <p><b>Notes for all population subgroups:</b></p> <ul style="list-style-type: none"> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul> <hr/> <p><b><u>Restricted Benefit</u></b> Nicotine dependence</p> <p><b>PATCH</b> <b>General Population</b> <b>Clinical criteria:</b></p> <ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have indicated they are ready to cease smoking, AND</li> <li>•Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.</li> </ul> <p><b>Treatment criteria:</b></p> <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated. Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</li> </ul> <p><b>Aboriginal or a Torres Strait Islander person</b> <b>Population criteria:</b></p> <ul style="list-style-type: none"> <li>•Patient must be an Aboriginal or a Torres Strait Islander person.</li> </ul> <p><b>Clinical criteria:</b></p> <ul style="list-style-type: none"> <li>•The treatment must be the sole PBS-subsidised therapy for this condition.</li> </ul>
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Items	Restriction
	<p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>•Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.</li> <li>•Benefit is improved if used in conjunction with a comprehensive support and counselling program.</li> </ul> <p><b>Notes for General Population &amp; Aboriginal or Torres Strait Islander person:</b></p> <ul style="list-style-type: none"> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul>
<b>NICOTINE LOZENGE/PATCH/GUM</b>	<p><b>Authority Required</b> Nicotine dependence</p> <p><b>Repatriation Listings – PATCH (7 pack)</b></p> <p><b>Clinical criteria:</b></p> <ul style="list-style-type: none"> <li>•Patient must have indicated they are ready to cease smoking, AND</li> <li>•Patient must have entered a comprehensive support and counselling program.</li> </ul> <p><b>Note:</b> Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.</p>

## PBS restrictions for smoking cessation therapies

Items	Restriction	Prescriber
<b>8465M Bupropion</b> hydrochloride 150 mg modified release tablet, 30	<p><b>Authority Required (STREAMLINED)</b> Nicotine dependence Treatment Phase: Commencement of a short-term (9 weeks) course of treatment Clinical criteria:</p> <ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have indicated they are ready to cease smoking, AND</li> <li>•Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.</li> </ul> <p>Treatment criteria:</p> <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated. Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</li> </ul> <p>Notes:</p> <ul style="list-style-type: none"> <li>•Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.</li> <li>•The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.</li> <li>•A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.</li> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul>	Medical Practitioner Nurse Practitioner
<b>8710K Bupropion</b> hydrochloride 150 mg modified release tablet, 90	<p><b>Authority Required (STREAMLINED)</b> Nicotine dependence Treatment Phase: Completion of a short-term (9 weeks) course of treatment Clinical criteria:</p> <ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> </ul>	Medical Practitioner Nurse Practitioner

Items	Restriction	Prescriber
	<ul style="list-style-type: none"> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, AND</li> <li>•Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.</li> </ul> <p>Treatment criteria:</p> <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.</li> </ul> <p>Notes:</p> <ul style="list-style-type: none"> <li>•Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.</li> <li>•The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.</li> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul>	
<p><b>9128K</b>  <b>Varenicline 500</b>  microgram tablet [11]  (&amp;) <b>varenicline 1 mg</b>  tablet [42], 53</p>	<p><b><u>Authority Required (STREAMLINED)</u></b>  Nicotine dependence  Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment  Clinical criteria:</p> <ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have indicated they are ready to cease smoking, AND</li> <li>•Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period.</li> </ul> <p>Treatment criteria:</p> <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated. Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</li> </ul> <p>Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.</p> <p>Notes:</p> <ul style="list-style-type: none"> <li>•A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.</li> <li>•The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.</li> <li>•A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.</li> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul>	<p>Medical  Practitioner  Nurse  Practitioner</p>
<p><b>5469W</b>  <b>Varenicline 1 mg tablet,</b>  56</p>	<p><b><u>Authority Required (STREAMLINED)</u></b>  Nicotine dependence  Treatment Phase: Completion of a short-term (24 weeks) course of treatment  Clinical criteria:</p> <ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, AND</li> <li>•Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.</li> </ul>	<p>Medical  Practitioner  Nurse  Practitioner</p>

Items	Restriction	Prescriber
	<p>Treatment criteria:</p> <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.</li> </ul> <p>Notes:</p> <ul style="list-style-type: none"> <li>•A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.</li> <li>•A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.</li> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul>	
<p><b>9129L</b>  <b>Varenicline</b> 1 mg tablet,  56</p>	<p><b>Authority Required (STREAMLINED)</b></p> <p>Nicotine dependence  Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment  Clinical criteria:</p> <ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have previously received treatment with this drug during this current course of treatment.</li> </ul> <p>Treatment criteria:</p> <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.</li> </ul> <p>Notes:</p> <ul style="list-style-type: none"> <li>•A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.</li> <li>•A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.</li> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised</li> </ul>	<p>Medical  Practitioner  Nurse  Practitioner</p>
<p><b>11619M</b>  <b>Nicotine</b> 4 mg lozenge,  216</p>	<p><b>Restricted Benefit</b></p> <p>Nicotine dependence  1. Population criteria:</p> <ul style="list-style-type: none"> <li>•Patient must be an Aboriginal or a Torres Strait Islander person.</li> </ul> <p>Clinical criteria:</p> <ul style="list-style-type: none"> <li>•The treatment must be the sole PBS-subsidised therapy for this condition.</li> </ul> <p>Notes:</p> <ul style="list-style-type: none"> <li>•Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.</li> <li>•Benefit is improved if used in conjunction with a comprehensive support and counselling program.</li> </ul> <p>2. Clinical criteria:</p> <ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have indicated they are ready to cease smoking, AND</li> <li>•Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.</li> </ul> <p>Treatment criteria:</p> <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.</li> <li>•Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</li> </ul> <p>Notes 1 &amp; 2:</p>	<p>Medical  Practitioner  Nurse  Practitioner</p>



Items	Restriction	Prescriber
	<ul style="list-style-type: none"> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul>	
<p><b>4573Q</b>  <b>Nicotine</b> 21 mg/24 hours patch, 7</p>	<p><b><u>Authority Required</u></b>  Nicotine dependence  Clinical criteria:  •Patient must have indicated they are ready to cease smoking, AND  •Patient must have entered a comprehensive support and counselling program.</p> <p>Note:  •Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program</p>	<p>Medical Practitioner</p>
<p><b>11612E</b>  <b>Nicotine</b> 4 mg chewing gum, 216</p>	<p><b><u>Restricted Benefit</u></b>  Nicotine dependence  1. Population criteria:  •Patient must be an Aboriginal or a Torres Strait Islander person.  Clinical criteria:  •The treatment must be the sole PBS-subsidised therapy for this condition.  Notes:  •Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.  •Benefit is improved if used in conjunction with a comprehensive support and counselling program.</p> <p>2. Clinical criteria:  •The treatment must be as an aid to achieving abstinence from smoking, AND  •The treatment must be the sole PBS-subsidised therapy for this condition, AND  •Patient must have indicated they are ready to cease smoking, AND  •Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.  Treatment criteria:  •Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.  •Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</p> <p>Notes 1 &amp; 2:  •No increase in the maximum quantity or number of units may be authorised.  •No increase in the maximum number of repeats may be authorised.</p>	<p>Medical Practitioner  Nurse Practitioner</p>
<p><b>5573H</b>  <b>Nicotine</b> 7 mg/24 hours patch, 28</p>	<p><b><u>Restricted Benefit</u></b>  Nicotine dependence  Clinical criteria:  •The treatment must be as an aid to achieving abstinence from smoking, AND  •The treatment must be the sole PBS-subsidised therapy for this condition, AND  •Patient must have indicated they are ready to cease smoking, AND  •Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.  Treatment criteria:  •Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.  •Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</p> <p>Notes:  •No increase in the maximum quantity or number of units may be authorised.</p>	<p>Medical Practitioner  Nurse Practitioner</p>

Items	Restriction	Prescriber
<p><b>10076H</b>  <b>Nicotine</b> 25 mg/16 hours patch, 28</p>	<p>•No increase in the maximum number of repeats may be authorised.</p> <p><b>Restricted Benefit</b>  Nicotine dependence  1. Population criteria:  •Patient must be an Aboriginal or a Torres Strait Islander person.  Clinical criteria:  •The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Notes:  •Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.  •Benefit is improved if used in conjunction with a comprehensive support and counselling program.</p> <p>2. Clinical criteria:  •The treatment must be as an aid to achieving abstinence from smoking, AND  •The treatment must be the sole PBS-subsidised therapy for this condition, AND  •Patient must have indicated they are ready to cease smoking, AND  •Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.  Treatment criteria:  •Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.  •Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</p> <p>Notes 1 &amp; 2:  •No increase in the maximum quantity or number of units may be authorised.  •No increase in the maximum number of repeats may be authorised.</p>	<p>Medical Practitioner  Nurse Practitioner</p>
<p><b>11617K</b>  <b>Nicotine</b> 2 mg lozenge, 216</p>	<p><b>Restricted Benefit</b>  Nicotine dependence  1. Population criteria:  •Patient must be an Aboriginal or a Torres Strait Islander person.  Clinical criteria:  •The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Notes:  •Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.  •Benefit is improved if used in conjunction with a comprehensive support and counselling program.</p> <p>2. Clinical criteria:  •The treatment must be as an aid to achieving abstinence from smoking, AND  •The treatment must be the sole PBS-subsidised therapy for this condition, AND  •Patient must have indicated they are ready to cease smoking, AND  •Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.  Treatment criteria:  •Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.  •Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</p> <p>Notes 1 &amp; 2:</p>	<p>Medical Practitioner  Nurse Practitioner</p>

Items	Restriction	Prescriber
	<ul style="list-style-type: none"> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul>	
<p><b>3414Q</b>  <b>Nicotine</b> 21 mg/24 hours patch, 28</p>	<p><b>Restricted Benefit</b>  Nicotine dependence  Clinical criteria:  <ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have indicated they are ready to cease smoking, AND</li> <li>•Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.</li> </ul> Treatment criteria:  <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.</li> <li>•Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</li> </ul> Notes:  <ul style="list-style-type: none"> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul> </p>	<p>Medical Practitioner  Nurse Practitioner</p>
<p><b>5465P</b>  <b>Nicotine</b> 21 mg/24 hours patch, 28</p>	<p><b>Restricted Benefit</b>  Nicotine dependence  1. Population criteria:  <ul style="list-style-type: none"> <li>•Patient must be an Aboriginal or a Torres Strait Islander person.</li> </ul> Clinical criteria:  <ul style="list-style-type: none"> <li>•The treatment must be the sole PBS-subsidised therapy for this condition.</li> </ul> Notes:  <ul style="list-style-type: none"> <li>•Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.</li> <li>•Benefit is improved if used in conjunction with a comprehensive support and counselling program.</li> </ul> 2. Clinical criteria:  <ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have indicated they are ready to cease smoking, AND</li> <li>•Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.</li> </ul> Treatment criteria:  <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.</li> <li>•Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</li> </ul> Notes 1 &amp; 2:  <ul style="list-style-type: none"> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul> </p>	<p>Medical Practitioner  Nurse Practitioner</p>
<p><b>5571F</b>  <b>Nicotine</b> 21 mg/24 hours patch, 28</p>	<p><b>Restricted Benefit</b>  Nicotine dependence  Population criteria:  <ul style="list-style-type: none"> <li>•Patient must be an Aboriginal or a Torres Strait Islander person.</li> </ul> Clinical criteria:  <ul style="list-style-type: none"> <li>•The treatment must be the sole PBS-subsidised therapy for this condition.</li> </ul> Notes:</p>	<p>Medical Practitioner  Nurse Practitioner</p>

Items	Restriction	Prescriber
	<ul style="list-style-type: none"> <li>•Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.</li> </ul> Benefit is improved if used in conjunction with a comprehensive support and counselling program. <ul style="list-style-type: none"> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul>	
<b>11618L</b> <b>Nicotine 2 mg chewing gum, 216</b>	<p><b><u>Restricted Benefit</u></b></p> Nicotine dependence 1. Population criteria: <ul style="list-style-type: none"> <li>•Patient must be an Aboriginal or a Torres Strait Islander person.</li> </ul> Clinical criteria: <ul style="list-style-type: none"> <li>•The treatment must be the sole PBS-subsidised therapy for this condition.</li> </ul> <p>Notes:</p> <ul style="list-style-type: none"> <li>•Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.</li> <li>•Benefit is improved if used in conjunction with a comprehensive support and counselling program.</li> </ul> <p>2.Clinical criteria:</p> <ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have indicated they are ready to cease smoking, AND</li> <li>•Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.</li> </ul> Treatment criteria: <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.</li> <li>•Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</li> </ul> <p>Notes 1 &amp; 2:</p> <ul style="list-style-type: none"> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul>	Medical Practitioner Nurse Practitioner
<b>4572P</b> <b>Nicotine 14 mg/24 hours patch, 7</b>	<p><b><u>Authority Required</u></b></p> Nicotine dependence Clinical criteria: <ul style="list-style-type: none"> <li>•Patient must have indicated they are ready to cease smoking, AND</li> <li>•Patient must have entered a comprehensive support and counselling program.</li> </ul> <p>Note:</p> <ul style="list-style-type: none"> <li>•Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.</li> </ul>	Medical Practitioner
<b>4571N</b> <b>Nicotine 7 mg/24 hours patch, 7</b>	<p><b><u>Authority Required</u></b></p> Nicotine dependence Clinical criteria: <ul style="list-style-type: none"> <li>•Patient must have indicated they are ready to cease smoking, AND</li> <li>•Patient must have entered a comprehensive support and counselling program.</li> </ul> <p>Note:</p> <ul style="list-style-type: none"> <li>•Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.</li> </ul>	Medical Practitioner
<b>5572G</b> <b>Nicotine 14 mg/24 hours patch, 28</b>	<p><b><u>Restricted Benefit</u></b></p> Nicotine dependence Clinical criteria:	Medical Practitioner

Items	Restriction	Prescriber
	<ul style="list-style-type: none"> <li>•The treatment must be as an aid to achieving abstinence from smoking, AND</li> <li>•The treatment must be the sole PBS-subsidised therapy for this condition, AND</li> <li>•Patient must have indicated they are ready to cease smoking, AND</li> <li>•Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.</li> </ul> <p>Treatment criteria:</p> <ul style="list-style-type: none"> <li>•Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.</li> <li>•Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</li> </ul> <p>Notes:</p> <ul style="list-style-type: none"> <li>•No increase in the maximum quantity or number of units may be authorised.</li> <li>•No increase in the maximum number of repeats may be authorised.</li> </ul>	Nurse Practitioner