

Pharmaceutical Benefits Scheme

Post-market Review

Post-market Review of Medicines Used for Smoking Cessation

Report to PBAC

Background

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Abbreviations

| Abbreviation | Full Name / Wording |
|--------------|--|
| CMI | Consumer Medicines Information |
| MBS | Medicare Benefits Schedule |
| NRT | Nicotine Replacement Therapy |
| PBAC | Pharmaceutical Benefits Advisory Committee |
| PBS | Pharmaceutical Benefits Scheme |
| PMR | Post-Market Review |
| RAAHS | Remote Area Aboriginal Health Services |
| RG | Reference Group |
| RPBS | Repatriation Schedule of Pharmaceutical Benefits |
| TGA | Therapeutic Goods Administration |
| ToR | term of reference |

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Expert Reference Group:

Membership listed in Appendix A – Reference Group Members

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Report Structure

This Report is presented in several parts, as briefly outlined below. The Report has been structured in this way to address the Terms of Reference (ToRs) of the Review.

Background: Provides the context for the Review, a brief description of nicotine dependence; the listing history for Pharmaceutical Benefits Scheme (PBS) listed medicines for smoking cessation; and the research questions supporting the Review's ToRs.

Report Summary: Provides a summary of the key findings from the Review.

Section 1 – ToR 1: Collates the current clinical guidelines for medicines for smoking cessation and compares these to the Therapeutic Goods Administration (TGA) and PBS restrictions for these medicines.

Section 2 – ToR 2: Reviews the utilisation of PBS-listed medicines for smoking cessation including but not limited to patient demographics, time on treatment, and the proportion using PBS subsidised combination treatment.

Section 3 – ToR 3: Reviews the efficacy and safety of nicotine replacement therapy, varenicline and bupropion for smoking cessation including combination therapies not currently PBS subsidised.

Section 4 – ToR 4 (possible future report): Subject to the findings of Terms of Reference 1, 2 and 3, review the cost-effectiveness of medicines for smoking cessation.

Background

B.1 Post-market monitoring

The Post-Market Review (PMR) program is a systematic approach to monitoring medicines subsidised by the PBS. PMRs were initiated under the 2011-12 Budget measure 'Improving sustainability of the PBS through enhanced post-market surveillance.'

PMRs are established under the quality use of medicines objective of the National Medicines Policy framework; promoting the safe and effective use of medicines, with the aim to improve health outcomes for all Australians.

The PMR program contributes to the following:

- Improved patient safety through better understanding of adverse events and medicine-related harms, including hospitalisations;
- A more sustainable PBS through better targeting of medicines, and avoidance of preventable wastage, or inappropriate prescribing;
- A better knowledge base to understand medicines utilisation, to validate the intended clinical benefit which will inform medicines evaluation processes; and
- A strengthened approach to medicine pricing management, including through better management of clinical and economic uncertainty.

Post-market reviews can be initiated when concerns related to the quality use of a medicine, cost-effectiveness, clinical effectiveness, higher than predicted utilisation and/or international differences are raised. A full post-market review will only proceed following PBAC agreement and Ministerial approval.

B.2 Context of the Review

There are currently three pharmacological interventions for smoking cessation available on the Pharmaceutical Benefits Scheme (PBS): nicotine replacement therapy (NRT) (in patch, gum and lozenge form), varenicline and bupropion.

In the financial year for 2019/2020;

- 1.2% of the Australian population (265,544 people) were supplied 542,492 prescriptions for PBS subsidised smoking cessation therapies.
- Three people per 1,000 in the Australian population (65,543 people) made their first ever attempt at quitting with PBS subsidised smoking cessation therapy.
- \$36 million in R/PBS benefits was paid for smoking cessation therapy.

In July 2017, the Pharmaceutical Benefits Advisory Committee (PBAC) deferred a major submission for the listing of NRT in the form of gum and lozenges (2mg and 4mg strengths) on the PBS. The PBAC noted that the efficacy of nicotine lozenges and gum significantly improved when used in combination with nicotine patches, but that no evidence was provided in the submission about the cost-effectiveness of combination NRT.

In March 2018, the PBAC recommended the listing of nicotine gum and lozenges as monotherapies on the PBS for treating nicotine dependence. The PBAC considered that a broader review of PBS-listed nicotine dependence treatments, in the context of the current clinical guidelines, would help inform whether the current subsidy arrangements should be altered to better support smoking cessation.

The post-market review of medicines for smoking cessation was approved by the Minister for Health on 18 September 2019.

B.3 Review Process

B.3.1 Purpose of the Review

The Review has the overall aim of continuing safe and cost-effective access to medicines for smoking cessation.

B.3.2 Review Reference Group

A Reference Group is formed to assist in the review of the evidence and information for each of the Review's terms of reference, and to ensure that the perspectives of stakeholders are considered in its preparation of the final report to the PBAC. The Reference Group may provide the PBAC with options to address key findings. Members of the Reference Group are appointed as either individuals or organisational representatives. Representation includes clinical experts, health economists and representatives of relevant health professional and consumer organisations. The Reference group for the Review was appointed on 22 April 2020. A full list of Reference Group members is provided in the final report published on the PBS website at Appendix A – Reference Group Members.

B.3.3 Review Terms of Reference

The Review's draft Terms of Reference (ToRs) were open to public consultation from 21 October 2019 to 25 November 2019. Nine submissions were received from peak bodies. Except where requested otherwise, public comments were published on the Review's website.

The PBAC considered the draft ToRs and comments from stakeholders in December 2019. In February 2020, the Minister for Health approved the final ToRs. Research questions relating to the ToRs were developed to guide the technical review, and were discussed and further refined by the RG at their first two meetings on 2 June 2020 and 29 September 2020. The final ToRs and research questions, approved by the RG Chair, are listed below.

E-cigarette devices and nicotine liquids are outside the scope of the PMR and this has been explicitly stated in the review terms of reference. In addition, e-cigarettes are not currently listed on the PBS.

When the ToRs were approved by the Minister in September 2019 no e-cigarette products had been TGA approved for marketing as a therapeutic good for smoking cessation in Australia. In order for a medicine to be considered for listing on the PBS to treat a given

condition, that medicine has to be registered in Australia by the Therapeutic Goods Administration (TGA) for the treatment of that condition.

Term of reference 1

ToR 1: Collate the current clinical guidelines for medicines for smoking cessation and compare these to the Therapeutic Goods Administration (TGA) and PBS restrictions for these medicines.

Term of reference 2

ToR 2: Review the utilisation of PBS-listed medicines for smoking cessation including but not limited to patient demographics, time on treatment, and the proportion using PBS subsidised combination treatment.

Term of reference 3

ToR 3: Review the efficacy and safety of nicotine replacement therapy, varenicline and bupropion for smoking cessation including combination therapies not currently PBS subsidised.

Term of reference 4

ToR 4: Subject to the findings of Terms of Reference 1, 2 and 3, review the cost-effectiveness of medicines for smoking cessation.

A possible future report may consider the cost-effectiveness of one or more PBS subsidised medicines for smoking cessation. A decision to undertake a cost-effectiveness review will be made by the PBAC when considering this report addressing ToRs 1-3.

B.3.4 Public submissions

Public submissions addressing the ToRs for this Review were open from 16 March 2020 to 1 May 2020. This process provided stakeholders with an opportunity to identify relevant issues, evidence or data that may inform the Review. Submissions were received from 11 peak bodies and two pharmaceutical companies. Except where requested otherwise, public submissions were published on the Review's website.

The content of the public submissions was considered in the development of the report and incorporated into the review where appropriate. Overall, the clinical evidence provided in the public submissions was similar to those identified in the reviews of the literature addressing each term of reference.

B.3.5 Stakeholder Forum

A Stakeholder Forum for the Review was held by the Department of Health via webinar, on 3 December 2020. The discussion from the Stakeholder Forum is summarised in the ToRs key findings. A full version of the Stakeholder Forum Summary is available on the Review's website: pbs.gov.au/reviews.

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 of treatment per year; and
- 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; and
- the high cost of smoking cessation therapy.

B.4 Medicines for smoking cessation

B.4.1 Description of the condition

Nicotine dependence

Most tobacco smokers are addicted to nicotine. This addiction is a chronic disease state that is prone to relapses and remissions (1). The majority of people who smoke begin smoking in their youth, and initiation during this period can be particularly detrimental as children and young people who are exposed to nicotine can become addicted at lower and more intermittent levels of tobacco consumption in comparison to adults (2). Nicotine exposure during adolescence may also have damaging and long-term impacts on brain development, and can lead to addiction that causes young people to continue smoking for longer and at higher intensities. These factors are strongly associated with tobacco-related disease and premature death (3).

According to the 2019 National Drug Strategy Household Survey (NDSHS) conducted by the Australian Institute of Health and Welfare (AIHW), 11.0% of Australians aged 14 years and over smoked daily, a significant decrease from 24.3% in 1991. Despite the long-term progress Australia has made in reducing smoking prevalence, tobacco remains the leading cause of death and disability in Australia. In 2015, cigarette smoking was responsible for 9.3% of the total burden of disease and injury, and more than 1 in every 10 (21,000) deaths (4).

Tobacco use compounds health and social inequalities and is a major contributor to poorer health status in socioeconomically disadvantaged populations. The most recent available estimates of the overall social (including health) costs of tobacco use in Australia were \$137

billion in 2015-16, including \$19.2 billion in tangible costs and \$117.7 billion in intangible costs (5).

B.4.2 Description of the intervention.

This Post-market Review will focus on medicines for smoking cessation that are listed on the PBS. The medicines for smoking cessation listed on the PBS are presented in Table B.1 along with their PBS item numbers and form of administration.

Table B.1: Medicines for smoking cessation listed on the PBS*

| Active ingredient | Brand name, strength [pack size] | Company/ PBS Item number | Administration |
|------------------------------------|--|--|-----------------------|
| Nicotine replacement therapy (NRT) | Nicorette 16hr Invisipatch®, 25mg/16 hours [28] | Johnson & Johnson Pacific Pty Limited (10076H) | Patch |
| | Nicotinell Step 2®, 14mg/24 hours [28] | Orion Laboratories Pty Ltd (5572G) | |
| | Nicotinell Step 1®, 21mg/24 hours [28] | Orion Laboratories Pty Ltd (3414Q; 5571F) | |
| | Nicabate P®, 21mg/24 hours [28] | GlaxoSmithKline Australia Pty Ltd (5465P) | |
| | Nicotinell Step 3®, 7mg/24 hours [28] | Orion Laboratories Pty Ltd (5573H) | |
| | Nicabate CQ 14®, 14mg/24 hours [7] ^a | GlaxoSmithKline Australia Pty Ltd (4572P) | |
| | QuitX® 14mg/24 hours [7] ^a | Alphapharm Pty Ltd (4572P) | |
| | QuitX® 7mg/24 hours [7] ^a | Alphapharm Pty Ltd (4571N) | |
| Nicotine replacement therapy (NRT) | Nicotinell®, 2mg [216] | Orion Laboratories Pty Ltd (11617K) | Lozenge |
| | Nicotinell®, 4mg [216] | Orion Laboratories Pty Ltd (11619M) | |
| Nicotine replacement therapy (NRT) | Nicotinell®, 2mg [216] | Orion Laboratories Pty Ltd (11618L) | Chewing gum |
| | Nicotinell®, 4mg [216] | Orion Laboratories Pty Ltd (11612E) | |
| Varenicline | Champix®, 500microgram tablet [11] (& varenicline 1mg tablet [42] ^b | Pfizer Australia Pty Ltd (9128K) | Tablet |

| | | | |
|-----------|---|--|-------------------------|
| | Champix®, varenicline 1mg [56] ^c | Pfizer Australia Pty Ltd (5469W; 9129L) | |
| Bupropion | Zyban®, 150mg [30] Zyban®, 150mg [90] | Aspen Pharmacare Australia Pty Limited (8465M) Aspen Pharmacare Australia Pty Limited (8710K) | Modified release tablet |

* Effective 24 December 2020

^a Repatriation Care items ^b Initiation Pack ^c Continuation Pack

Nicotine Replacement Therapy (NRT)

Nicotine acts primarily on cholinergic receptors of the nicotine type in the peripheral and central nervous system. Nicotine, the chief alkaloid in tobacco products, bind stereo selectively to acetylcholine receptors at the autonomic ganglia, in the adrenal medulla, at neuromuscular junctions and in the brain. Two types of central nervous system effects are believed to be the basis of nicotine's positively reinforcing properties. A stimulating effect, exerted mainly in the cortex via the locus ceruleus, produces increased alertness and cognitive performance. A "reward" effect via the "pleasure system" in the brain is exerted in the limbic system. At low doses the stimulant effects predominate while, at high doses, the reward effects predominate (6).

NRT patch has been designed to slowly allow nicotine to be absorbed by the body to offset the physical withdrawal symptoms of smoking cessation. It is easier to withdraw off NRT than cigarettes due to the lower levels of nicotine present. Short-acting forms of NRT (gum, inhalation cartridge, lozenge, oral spray and sublingual tablet) give a rapid increase in blood nicotine concentration, similar to that associated with smoking, and may be helpful for the more nicotine-dependent smokers. Nicotine patches do not produce this rapid increase, which people trying to quit may crave (7).

Varenicline

Varenicline is a partial agonist at $\alpha 4\beta 2$ neuronal nicotinic acetylcholine receptors where it binds with high affinity and selectivity to produce an effect sufficient to alleviate symptoms of craving and withdrawal (agonist activity), while simultaneously resulting in blockade of the rewarding and reinforcing effects of smoking by preventing nicotine binding to $\alpha 4\beta 2$ receptors (antagonist activity) (8).

Bupropion

Bupropion is a selective inhibitor of the neuronal re-uptake of catecholamines (noradrenaline and dopamine) with minimal effect on the re-uptake of indolamines (serotonin) and no inhibitory effect on monoamine oxidase. The mechanism by which bupropion enhances the ability of patients to abstain from smoking is unknown. However, it is presumed that this action is mediated by noradrenergic and/or dopaminergic mechanisms (9).

B.4.3 Cost of smoking cessation therapy

Medicines for smoking cessation are subsidised on the PBS to provide financial support to help people quit smoking. These products include NRT (in patch, gum and lozenge form), varenicline and bupropion. The medicines listed in the PBS are described in section B.4.2. The PBS restrictions for these medicines are outline in section B.4.5.

Consumer may also access NRT over the counter in pharmacies and supermarkets. The relative costs of accessing smoking cessation medicines on the PBS and over the counter are described in table B.2.

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Table B.2: Cost of smoking cessation medicines

| Medicine | Brand (pack size/quantity) | Price/PBS DPMQ | Source | PBS DPMQ for 1 course of treatment ^{2,3} | Patient contribution (cost to consumer) for 1 course of treatment ^{2,3} | Cost to PBS/RPBS for 1 course of treatment per patient ^{2,3} | |
|--------------------------|---|------------------------|-----------------------------------|---|--|---|--|
| Nicotine 21mg/24hr patch | Nicotinell Step 1 (28) | \$49.90 | PBS DPMQ | \$149.70 | \$123.90 (general pt) \$19.80 (concession pt) | \$25.80 (general pt) \$129.90 (concession pt) | |
| | | \$60.49 | Chemist Warehouse – private rx | Non-PBS | \$181.47 | Non-PBS | |
| | Nicabate P (28) | \$49.90 | PBS DPMQ | \$149.70 | \$123.90 (general pt) \$19.80 (concession pt) | \$25.80 (general pt) \$129.90 (concession pt) | |
| | | \$50.49 | Chemist Warehouse – private rx | Non-PBS | \$151.47 | Non-PBS | |
| | Nicabate CQ 21 (7) | \$68.68 | PBS DPMQ ⁴ (RPBS only) | \$206.04 | \$19.80 (concessional rate via DVA card) | \$186.24 (DVA pt) | |
| | | \$29.99 | Chemist Warehouse – OTC | Non-PBS | \$359.88 | Non-PBS | |
| | | \$36.49 | Amcal – OTC | Non-PBS | \$437.88 | Non-PBS | |
| | Quit X (7) | \$58.62 | PBS DPMQ ⁴ (RPBS only) | \$175.86 | \$19.80 (concessional rate via DVA card) | \$156.06 (DVA pt) | |
| | | \$24.29 | Amcal – OTC | Non-PBS | \$291.48 | Non-PBS | |
| | Nicabate Clear Patch Quit Smoking Step 1 21mg Patches (7) | \$35 | Coles | Non-PBS | \$420 | Non-PBS | |
| | Nicotine 14mg/24hr patch | Nicotinell Step 2 (28) | \$49.90 | PBS DPMQ | \$149.70 | \$123.90 (general pt) \$19.80 (concession pt) | \$25.80 (general pt) \$129.90 (concession pt) |
| | | | \$58.15 | Amcal – OTC | Non-PBS | \$174.45 | Non-PBS |
| Nicabate CQ 14 (7) | | \$68.68 | PBS DPMQ ⁴ (RPBS only) | \$206.04 | \$19.80 (concessional rate via DVA card) | \$186.24 (DVA pt) | |
| | | \$29.99 | Chemist Warehouse – OTC | Non-PBS | \$359.88 | Non-PBS | |
| Quit X (7) | | \$55.66 | PBS DPMQ ⁴ (RPBS only) | \$166.98 | \$19.80 (concessional rate via DVA card) | \$147.18 (DVA pt) | |
| | | \$26.69 | Amcal – OTC | Non-PBS | \$320.28 | Non-PBS | |

| Medicine | Brand (pack size/quantity) | Price/PBS DPMQ | Source | PBS DPMQ for 1 course of treatment ^{2,3} | Patient contribution (cost to consumer) for 1 course of treatment ^{2,3} | Cost to PBS/RPBS for 1 course of treatment per patient ^{2,3} |
|---------------------------------------|---|----------------|---|---|--|---|
| | Nicabate Clear Patch Quit Smoking Step 2 Patches 14mg (7) | \$35 | Coles | Non-PBS | \$420 | Non-PBS |
| Nicotine 7mg/24hr patch ⁵ | Nicotinell Step 3 (28) | \$49.90 | PBS DPMQ | \$149.70 | \$123.90 (general pt) \$19.80 (concession pt) | \$25.80 (general pt) \$129.90 (concession pt) |
| | | \$60.49 | Chemist Warehouse – private rx | Non-PBS | \$181.47 | Non-PBS |
| | | \$58.14 | Amcal – OTC | Non-PBS | \$174.42 | Non-PBS |
| | Quit X (7) | \$52.50 | PBS DPMQ ⁴ (RPBS only) | \$157.50 | \$19.80 (concessional rate via DVA card) | \$137.70 (DVA pt) |
| | | \$24.09 | Amcal – OTC | Non-PBS | \$289.08 | Non-PBS |
| Nicotine 25mg/16hr patch ⁵ | Nicorette 16hr Invisipatch (28) | \$49.90 | PBS DPMQ | \$149.70 | \$123.90 (general pt) \$19.80 (concession pt) | \$25.80 (general pt) \$129.90 (concession pt) |
| | | \$39.99 | Chemist Warehouse – OTC | Non-PBS | \$119.97 | Non-PBS |
| | Nicorette Invisipatch Step 1 25mg (7) | \$30 | Coles | Non-PBS | \$360 | Non-PBS |
| Nicotine Gum 2mg | Nicotinell (216) | \$68.84 | PBS DPMQ ⁶ (1 supply + 1 repeat permitted under the PBS. Each supply is for 2 packs of 216 pieces i.e. 432 pieces per supply.) | \$137.68 | \$82.60 (general pt) \$13.20 (concession pt) | \$55.08 (general pt) \$124.48 (concession pt) |
| | | \$44.99 | Chemist Discount Centre – OTC | Non-PBS | \$179.96 | Non-PBS |
| | Nicotinell (384) | \$32.99 | Chemist Warehouse – OTC | Non-PBS | \$98.97 | Non-PBS |
| | Nicotinell (96) | \$30.69 | Amcal – OTC | Non-PBS | \$276.21 | Non-PBS |
| | Nicabate Extra Fresh Mint Nicotine Chewing Gum 2mg (200) | \$40 | Coles | Non-PBS | \$200 | Non-PBS |
| | Nicabate Extra Fresh 2mg Gum (100) | \$28 | Coles | Non-PBS | \$252 | Non-PBS |

| Medicine | Brand (pack size/quantity) | Price/PBS DPMQ | Source | PBS DPMQ for 1 course of treatment ^{2,3} | Patient contribution (cost to consumer) for 1 course of treatment ^{2,3} | Cost to PBS/RPBS for 1 course of treatment per patient ^{2,3} |
|------------------|--|----------------|-------------------------------|---|--|---|
| | Nicorette Classic/Spearmint Gum 2mg (150) | \$48 | Coles | Non-PBS | \$288 | Non-PBS |
| | Nicorette Classic Gum (75) | \$29 | Coles | Non-PBS | \$348 | Non-PBS |
| | Nicabate Quit Smoking Extra Fresh Mint Gum 2 Mg (30) | \$13 | Woolworths | Non-PBS | \$364 | Non-PBS |
| Nicotine Gum 4mg | Nicotinell (216) | \$49.90 | PBS DPMQ | \$149.70 | \$123.90 (general pt) \$19.80 (concession pt) | \$25.80 (general pt) \$129.90 (concession pt) |
| | | \$44.99 | Chemist Discount Centre – OTC | Non-PBS | \$134.97 | Non-PBS |
| | Nicotinell (96) | \$32.79 | Amcal – OTC | Non-PBS | \$196.74 | Non-PBS |
| | Nicorette Icy Mint Gum (75) | \$29 | Coles | Non-PBS | \$232 | Non-PBS |
| | Nicabate Extra Fresh Mint Nicotine Chewing Gum 4mg (200) | \$40 | Coles | Non-PBS | \$120 | Non-PBS |
| | Nicabate Extra Fresh Mint Gum Quit Smoking 4mg (100) | \$28 | Coles Woolworths | Non-PBS | \$168 | Non-PBS |
| | Nicabate Chewing Gum 4mg 3x10 (30) | \$13 | Coles | Non-PBS | \$247 | Non-PBS |
| | Nicabate Quit Smoking Extra Fresh Mint Gum 4 Mg (30) | \$13 | Woolworths | Non-PBS | \$247 | Non-PBS |
| | Nicorette Classic/Spearmint Gum 4mg (150) | \$48 | Coles | Non-PBS | \$192 | Non-PBS |
| | Nicorette Classic Gum (75) | \$29 | Coles | Non-PBS | \$232 | Non-PBS |

| Medicine | Brand (pack size/quantity) | Price/PBS DPMQ | Source | PBS DPMQ for 1 course of treatment ^{2,3} | Patient contribution (cost to consumer) for 1 course of treatment ^{2,3} | Cost to PBS/RPBS for 1 course of treatment per patient ^{2,3} |
|---|---|--|---------------------|---|---|--|
| Nicotine Lozenge 2mg | Nicotinell (216) | \$49.90 | PBS DPMQ | \$149.70 | \$123.90 (general pt) \$19.80 (concession pt) | \$25.80 (general pt) \$129.90 (concession pt) |
| | Herron Nicaway Nicotine Lozenge 2mg (72) | \$20 | Coles Woolworths | Non-PBS | \$180 | Non-PBS |
| | Nicorette Cooldrops Freshfruit 2mg (80) | \$36 | Coles | Non-PBS | \$288 | Non-PBS |
| Nicotine Lozenge 4mg | Nicotinell (216) | \$49.90 | PBS DPMQ | \$149.70 | \$123.90 (general pt) \$19.80 (concession pt) | \$25.80 (general pt) \$129.90 (concession pt) |
| | Herron Nicaway Nicotine Lozenge 4mg (72) | \$20 | Coles Woolworths | Non-PBS | \$180 | Non-PBS |
| | Nicabate Minis Quit Smoking Lozenge 4mg (60) | \$28 | Coles | Non-PBS | \$280 | Non-PBS |
| | Nicabate Quit Smoking Minis Lozenge 4 Mg (60) | \$33.20 | Woolworths | Non-PBS | \$332 | Non-PBS |
| | Nicabate Minis Quit Smoking Lozenge 4mg (20) | \$12.80 | Coles Woolworths | Non-PBS | \$384 | Non-PBS |
| | Nicorette Cooldrops Freshfruit 4mg (80) | \$36 | Coles | Non-PBS | \$288 | Non-PBS |
| Varenicline 1 mg tablet Varenicline 500 microgram tablet & varenicline 1 mg tablet | Champix | (112, 1mg tablets=\$193.10; 11+42, 500mcg+1mg tablets=\$87.18) | PBS DPMQ | \$280.28 for first 12 weeks ⁷ | \$82.60 (general pt) \$13.20 (concession pt) - for first 12 weeks ⁷ | \$197.68 (general pt) \$267.08 (concession pt) - for first 12 weeks ⁷ |
| | | (56, 1mg tablets=\$100.63) | PBS DPMQ | \$301.89 for second 12 weeks ⁷ | \$123.90 (general pt) \$19.80 (concession pt) - for second 12 weeks ⁷ | \$177.99 (general pt) \$282.09 (concession pt) - for second 12 weeks ⁷ |

| Medicine | Brand (pack size/quantity) | Price/PBS DPMQ | Source | PBS DPMQ for 1 course of treatment ^{2,3} | Patient contribution (cost to consumer) for 1 course of treatment ^{2,3} | Cost to PBS/RPBS for 1 course of treatment per patient ^{2,3} |
|--|----------------------------|--|--|---|--|--|
| | | (56, 1mg tablets=\$96.39; 11+42, 500mcg+1mg tablets=\$81.69) | Chemist Warehouse – private rx | Non-PBS | \$274.47 for first 12 weeks ⁷ | Non-PBS |
| | | (56, 1mg tablets=\$96.39) | Chemist Warehouse – private rx (56, 1mg tablets=\$96.39) | Non-PBS | \$289.17 for second 12 weeks ⁷ | Non-PBS |
| Bupropion hydrochloride 150 mg modified release tablet | Zyban | (30 tablets=\$63.46; 90 tablets=\$169.05) | PBS DPMQ | \$232.51 | \$82.60 (general pt) \$13.20 (concession pt) – for bupropion one course = 9 weeks approx. ³ | \$149.91 (general pt) \$219.31 (concession pt) – for bupropion one course = 9 weeks approx. ³ |
| | | (30 tablets=\$60.69; 90 tablets=\$172.99) | Chemist Warehouse – private rx | Non-PBS | \$233.68 – for bupropion one course = 9 weeks approx. ³ | Non-PBS |

DPMQ = Dispensed price for maximum quantity; DVA = Department of Veterans' Affairs; hr = hour; mcg = microgram; OTC = over-the-counter; rx = prescription; pt = patient; RPBS = Repatriation Pharmaceutical Benefits Scheme; Shaded = Repatriation Pharmaceutical Benefits Scheme Listing

¹ Extracted from pbs.gov.au, Chemist Warehouse, Amcal, Chemist Discount Centre websites on 28 January 2021; extracted from Coles, Woolworths website on 12 February 2021.

² Quantity per course of treatment for nicotine replacement therapy (NRT) is based on dosing recommendations from the Australian Medicines Handbook (AMH) and provided below

³ One course of NRT and varenicline = 12 weeks; one course of bupropion is 61.5 days/8.79 weeks

⁴ Four packs dispensed/supplied at one time under the PBS

⁵ 7mg/24 hour patches and 25mg/16 hour patches were not included in the AMH recommendations for NRT. For the purposes of this table, it is assumed that 7mg/24 hour and 25mg/16 hour patches are dosed at one patch per day for 12 weeks.

⁶ Two packs dispensed/supplied at one time under the PBS

⁷ Two subsequent 12-week courses of varenicline are permitted for subsidy under the PBS

Aboriginal Health Services that are participating in the Remote Area Aboriginal Health Services (RAAHS) program are eligible to access nicotine products on the general PBS schedule and the PBS listing for Aboriginal and Torres Strait Islander patients and to supply these to clients without a PBS prescription and free of charge.

Consumers in non-remote areas who are participating in the Closing the Gap (CTG) Co-Payment Measure Program can also access all items on the PBS General Schedule, however under the CTG Co-Payment Measure Program, eligible patients who would normally pay the full PBS co-payment (\$41.30 per item in 2021) pay the concessional rate (\$6.60 per item in 2021). Those who would normally pay the concessional price receive their PBS medicines without being required to pay a PBS co-payment.

Consumers who meet the eligibility criteria can be registered for the CTG Co-Payment Measure Program by Indigenous Health Services located in urban and regional areas, or general practices participating in the Practice Incentives Program Indigenous Health Incentive (PIPI).

Consumers in Queensland may also access 12 weeks of NRT through the Intensive Quit Support program run by Quitline, as long as they meet eligibility criteria.

B.4.4 PBS listing history

The first listing of a medicine for smoking cessation were NRT patches on the Repatriation Schedule of Pharmaceutical Benefits (RPBS) in August 1994.

In September 2000, The PBAC recommended bupropion for listing with an authority required restriction "For use within a comprehensive treatment program with the goal of maintaining abstinence". The cost-effectiveness at the price proposed was considered acceptable.

Bupropion was subsequently listed in February 2001.

In July 2007, the PBAC recommended listing on the PBS of varenicline as a short-term treatment to aid smoking cessation on the basis of an acceptable cost-effectiveness compared with bupropion. Varenicline was subsequently listed in January 2008.

In March 2008, the PBAC recommended nicotine transdermal patches as an Authority required listing as the sole PBS-subsidised therapy for nicotine dependence in an Aboriginal or Torres Strait Islander person. The PBAC recommended only two courses of PBS-subsidised nicotine replacement therapy be authorised per year, noting that this population eschews oral aids for smoking cessation. Nicotine patches were subsequently listed for the Aboriginal or Torres Strait Islander population in December 2008.

In March 2010, the PBAC recommended the listing of nicotine transdermal patches on the PBS as an Authority required listing as an aid to cessation of smoking in patients who have entered or are entering a comprehensive support and counselling program in the context of a public health priority area, noting that reduction of chronic disease caused by smoking is

one of the key focuses of the national health taskforce on prevention. The PBAC recommended the listing of nicotine transdermal patches at the price requested in the submission on the basis of (a) non-inferior efficacy, superior safety and lower cost compared to bupropion, and (b) uncertain and possibly inferior efficacy, superior safety and lower cost compared to varenicline. Nicotine patches were subsequently listed for the general population in February 2011.

In March 2018, the PBAC recommended the listing of nicotine gum and lozenge, as monotherapies on the PBS as a restricted benefit for treating nicotine dependence in cigarette smokers who wish to quit and enter into a behavioural support program. The PBAC had previously accepted the submission's overall claim of non-inferiority in terms of comparative efficacy and safety for nicotine gum and lozenges compared with nicotine patches in July 2017, but deferred its decision at that time due to uncertainty in the estimation of equi-effective doses against the comparator, nicotine patches. Nicotine gum and lozenge were subsequently listed in February 2019.

Table B.2 presents a summary of the dates of recommendation and the basis of recommendation for medicines for smoking cessation.

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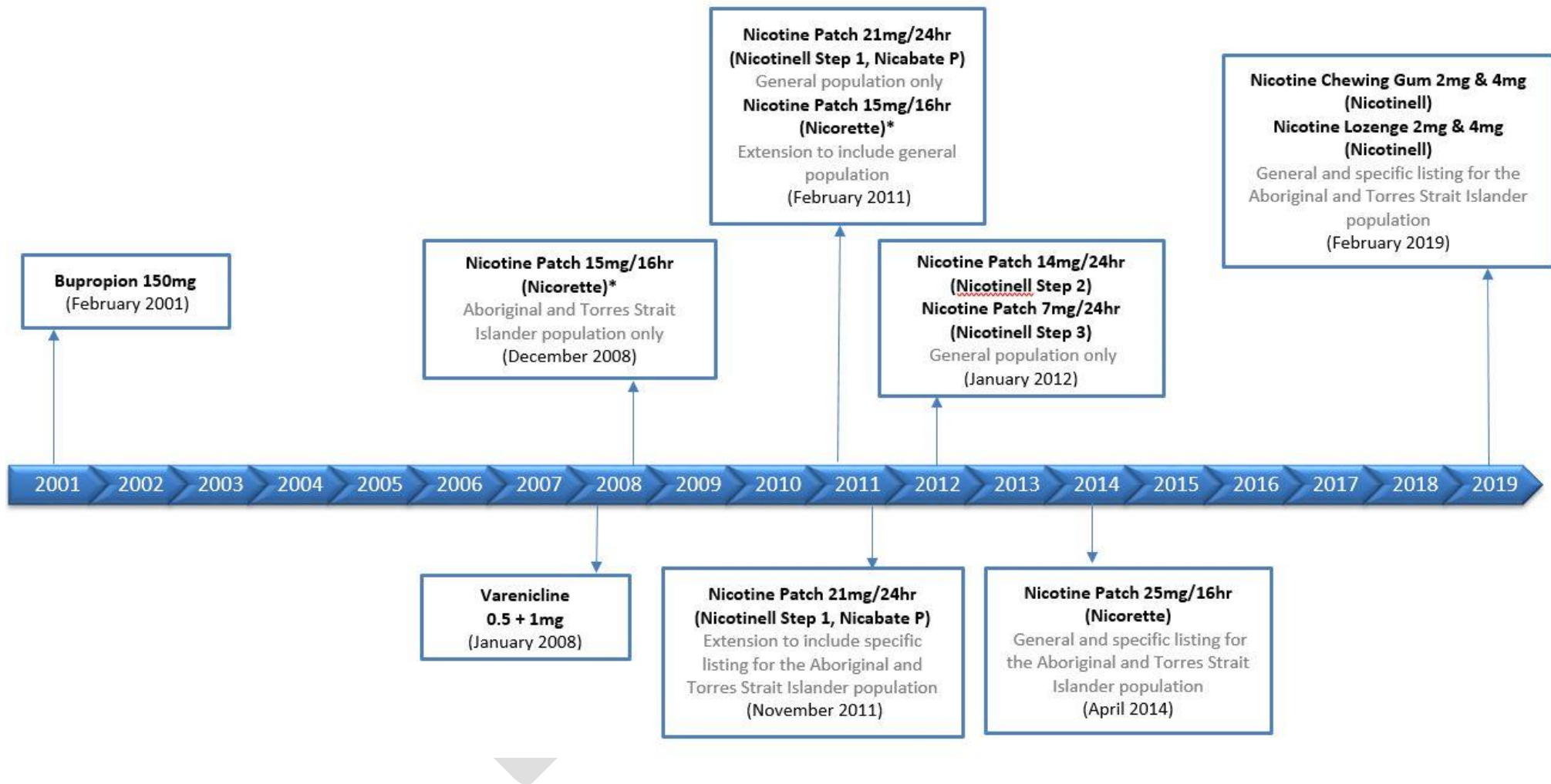


Figure B.1: Timeline for listings of medicines for smoking cessation on the PBS

* Delisted in July 2014

Table B.3: PBAC positive recommendation date and basis of key recommendation for PBS listed medicines for smoking cessation

| Medication | Presentation | Date recommended | Date of original PBS listing | Date/s of alterations to PBS restriction level (new restriction level) |
|------------------------------------|--|--|--|---|
| Bupropion | <ul style="list-style-type: none"> bupropion hydrochloride 150 mg modified release tablet, 90 bupropion hydrochloride 150 mg modified release tablet, 30 | <p><u>September 2000</u> Recommended for listing with an authority required restriction "For use within a comprehensive treatment program with the goal of maintaining abstinence". The cost-effectiveness [REDACTED] at the price proposed was considered acceptable.</p> | 22 August 2000 | <ul style="list-style-type: none"> 22 August 2000 (Authority Required) 1 October 2015 (Authority Required – <u>Streamlined</u>) |
| Varenicline | <ul style="list-style-type: none"> varenicline 500 microgram tablet [11] (& varenicline 1 mg tablet [42], 53 varenicline 1 mg tablet, 56 | <p><u>July 2007</u> The PBAC recommended listing on the PBS of varenicline as a short-term treatment to aid smoking cessation on the basis of an acceptable cost-effectiveness compared with bupropion.</p> | 1 January 2008 | <ul style="list-style-type: none"> 1 January 2008 (Authority Required) 1 May 2017 (Authority Required – <u>Streamlined</u>) |
| Nicotine Replacement Therapy (NRT) | <p><i>Patches</i></p> <ul style="list-style-type: none"> nicotine 7 mg/24 hours patch, 7 (RPBS only)¹ | <p><u>March 2008</u> The PBAC recommended an Authority required listing as the sole PBS-subsidised therapy for nicotine dependence in an Aboriginal or Torres Strait Islander person The PBAC recommended only 2 courses of PBS-subsidised nicotine</p> | <ul style="list-style-type: none"> 1 December 2008² 1 February 2011³ | <ul style="list-style-type: none"> 1 December 2008 for Aboriginal and Torres Strait Islander population only (Authority Required) |

¹ NRT patches have been available on the Repatriation Schedule of Pharmaceutical Benefits (RPBS) since 1 May 2000. Three strengths of the seven pack are currently listed on the RPBS (only) as an Authority Required benefit.

² For the Aboriginal and Torres Strait Islander population only

³ PBS access expanded to general population

| | | | | |
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| | <ul style="list-style-type: none"> • nicotine 21 mg/24 hours patch, 28 • nicotine 14 mg/24 hours patch, 28 • nicotine 14 mg/24 hours patch, 7 (RPBS only) • nicotine 7 mg/24 hours patch, 28 • nicotine 21 mg/24 hours patch, 7 (RPBS only) • nicotine 25 mg/16 hours patch, 28 | <p>replacement therapy be authorised per year, noting that this population eschews oral aids for smoking cessation.</p> <p><u>March 2010</u> The PBAC recommended listing in the context of a public health priority area, noting that reduction of chronic disease caused by smoking is one of the key focuses of the national health taskforce on prevention. The PBAC recommended the listing of nicotine transdermal patches at the price requested in the submission on the basis of (a) non-inferior efficacy, superior safety and lower cost compared to bupropion, and (b) uncertain and possibly inferior efficacy, superior safety and lower cost compared to varenicline. The PBAC recommended that the listing of nicotine patches be limited a maximum of 12 weeks treatment in a 12 month period.</p> | | <ul style="list-style-type: none"> • 1 February 2011 for general population (Authority Required) • 1 December 2013 (Authority Required - <u>Streamlined</u>) • 1 September 2015 (Restricted Benefit) |
| NRT | <p><i>Gum & Lozenges</i></p> <ul style="list-style-type: none"> • nicotine 2 mg chewing gum, 216 • nicotine 2 mg lozenge, 216 • nicotine 4 mg lozenge, 216 • nicotine 4 mg chewing gum, 216 | <p><u>March 2018</u> The PBAC recommended the listing of nicotine gum and lozenge on a cost-minimisation basis compared to transdermal patches, as monotherapies on the PBS as a restricted benefit for treating nicotine dependence in cigarette smokers who wish to quit and enter into a behavioural support program.</p> | <ul style="list-style-type: none"> • 1 February 2019 | <ul style="list-style-type: none"> • 1 February 2019 (Restricted Benefit) |

B.4.5 PBS prescribing restrictions

Current restrictions

Table B.4: Summary of prescribing restrictions for PBS-listed medicines for smoking cessation

| PBS ITEM | RESTRICTIONS |
|--|--|
| <p>BUPROPION</p> <ul style="list-style-type: none"> •bupropion hydrochloride 150 mg modified release tablet, 90 •bupropion hydrochloride 150 mg modified release tablet, 30 | <p><u>Authority Required (STREAMLINED)</u> Nicotine dependence</p> <p>Clinical criteria:</p> <ul style="list-style-type: none"> •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 9 weeks of PBS-subsidised treatment with this drug per 12-month period. AND •Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment (90 pack).* <p>Treatment criteria:</p> <ul style="list-style-type: none"> •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>Notes:</p> <ul style="list-style-type: none"> •Clinical review is recommended within 2 to 3 weeks of the original prescription being requested. •The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. •A patient may only qualify for PBS-subsidised treatment under this treatment phase (30 pack) restriction once during a short-term course of treatment. * •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>*Differences between pack sizes in bold above</p> |
| <p>VARENICLINE</p> <ul style="list-style-type: none"> •varenicline 1 mg tablet, 56 (continuation pack) •varenicline 500 microgram tablet [11] (& varenicline 1 mg tablet [42], 53 (initiation pack) | <p><u>Authority Required (STREAMLINED)</u> Nicotine dependence</p> <p>Clinical criteria:</p> <ul style="list-style-type: none"> •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 previously received PBS-subsidised treatment with this drug during this current course of treatment, AND •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 •Patient must have indicated they are ready to cease smoking (initiation pack). AND •Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period (initiation pack). |

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| | <p>Treatment criteria:</p> <ul style="list-style-type: none"> •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. •Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested. <p>Notes:</p> <ul style="list-style-type: none"> •A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. •A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment (continuation pack). •No increase in the maximum quantity or number of units may be authorised. •No increase in the maximum number of repeats may be authorised. •The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months (for initiation pack). <p>*Not required under one authority code</p> |
| <p>NICOTINE LOZENGE/PATCH/GUM</p> <ul style="list-style-type: none"> •nicotine 4 mg lozenge, 216 •nicotine 21 mg/24 hours' patch, 7* •nicotine 4 mg chewing gum, 216 •nicotine 7 mg/24 hours' patch, 28 •nicotine 25 mg/16 hours patch, 28 •nicotine 2 mg lozenge, 216 •nicotine 21 mg/24 hours' patch, 28 •nicotine 2 mg chewing gum, 216 •nicotine 14 mg/24 hours patch, 7* •nicotine 7 mg/24 hours patch, 7* •nicotine 14 mg/24 hours patch, 28 | <p>Restricted Benefit Nicotine dependence</p> <p>LOZENGE/GUM General Population Clinical criteria:</p> <ul style="list-style-type: none"> •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. <p>Treatment criteria:</p> <ul style="list-style-type: none"> •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>Aboriginal or a Torres Strait Islander person Population criteria:</p> <ul style="list-style-type: none"> •Patient must be an Aboriginal or a Torres Strait Islander person. <p>Clinical criteria:</p> <ul style="list-style-type: none"> •The treatment must be the sole PBS-subsidised therapy for this condition. <p>Notes:</p> <ul style="list-style-type: none"> •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>Notes for all population subgroups:</p> <ul style="list-style-type: none"> •No increase in the maximum quantity or number of units may be authorised. •No increase in the maximum number of repeats may be authorised. |

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| <p>*Repatriation Care Item</p> | <p><u>Restricted Benefit</u> Nicotine dependence</p> <p>PATCH General Population Clinical criteria:</p> <ul style="list-style-type: none"> •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. <p>Treatment criteria:</p> <ul style="list-style-type: none"> •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>Aboriginal or a Torres Strait Islander person Population criteria:</p> <ul style="list-style-type: none"> •Patient must be an Aboriginal or a Torres Strait Islander person. <p>Clinical criteria:</p> <ul style="list-style-type: none"> •The treatment must be the sole PBS-subsidised therapy for this condition. <p>Notes:</p> <ul style="list-style-type: none"> •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>Notes for General Population & Aboriginal or Torres Strait Islander person:</p> <ul style="list-style-type: none"> •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>NICOTINE LOZENGE/PATCH/GUM</p> | <p><u>Authority Required</u> Nicotine dependence</p> <p>Repatriation Listings – PATCH (7 pack)</p> <p>Clinical criteria:</p> <ul style="list-style-type: none"> •Patient must have indicated they are ready to cease smoking, AND •Patient must have entered a comprehensive support and counselling program. <p>Note: Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.</p> |

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Appendix A – Reference Group Members

| Name | Nominated By | Capacity of Appointment |
|------------|---|-------------------------|
| [REDACTED] | Department of Health | Chair |
| [REDACTED] | DUSC | Technical Expert |
| [REDACTED] | Department of Health | Technical Expert |
| [REDACTED] | Royal Australian College of General Practitioners | Technical Expert |
| [REDACTED] | Australian Health Economics Society | Technical Expert |
| [REDACTED] | Therapeutic Goods Administration | Organisational Nominee |
| [REDACTED] | Consumers Health Forum of Australia | Consumer Advocate |
| [REDACTED] | Medicines Australia | Organisational Nominee |

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