

4.06 NICOTINE, Gum 2 mg, Gum 4 mg, Lozenge 2 mg, Lozenge 4 mg, Nicotinell[®], Orion Laboratories Pty Ltd

1 Purpose of item

- 1.1 At the July 2017 PBAC meeting, the Committee considered a request that nicotine gum and lozenge be listed 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 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.
- 1.2 The PBAC deferred making a recommendation on whether nicotine gum and lozenges should be listed on the PBS as monotherapies for smoking cessation due to considerable uncertainty in the estimation of equi-effective doses for the formulations of NRT.
- 1.3 The PBAC advised that the Australian Medicines Handbook¹ (AMH) recommendations for the appropriate usage of nicotine replacement therapies (NRT) products be utilised in the estimation of equi-effective doses.

2 Equi-effective dose calculation

- 2.1 The PBAC noted that there are a number of challenges to calculating equi-effective monotherapy doses across NRT formulations due to the various levels of nicotine dependence and other confounding factors which may impact the effectiveness of NRT in an uncontrolled environment.
- 2.2 The PBAC acknowledged the difficulties associated with adequately capturing variations in adherence attributable to the different forms of NRT due to significant variability in patient characteristics and the high rates of relapse. On this basis the PBAC accepted that it was reasonable to assume patient adherence to be 100% for all formulations in determining the equi-effective doses using the AMH recommendations for NRT.
- 2.3 The doses were calculated using two nicotine dependence classifications; high and moderate dependence. It was assumed that patients will use a single strength formulation throughout the existing PBS subsidy which stipulates a maximum of 12 weeks of NRT annually.

¹ <https://amhonline.amh.net.au/chapters/chap-18/nicotine-dependence-drugs/nicotine?menu=hints>

Table 1: Estimated number of units for NRT required for a 12 week course of treatment

Form	Strength	Dose	AMH Dosing Recommendations + Assumptions
HIGH DEPENDENCE			
Gum	4mg	560	8 pieces/day for 8 weeks followed by a halving of the dose (cutting gum strip in half) for the next 4 weeks
Lozenge	4mg	588	Waking hours from 7am to 10pm (Total = 15hours) 10 pieces/day for 6 weeks then 5 pieces/day for 3 weeks then 3 pieces/day for 3 weeks
Patch	21mg	84	1 patch/day for 12 weeks
MODERATE DEPENDENCE			
Gum	2mg	840	10 pieces/day for 12 weeks
Lozenge	2mg	588	Waking hours from 7am to 10pm (Total = 15hours) 10 pieces/day for 6 weeks then 5 pieces/day for 3 weeks then 3 pieces/day for 3 weeks
Patch	14mg	84	1 patch/day for 12 weeks

Source: Calculated during the evaluation

3 Revised Cost Minimisation Analysis

3.1 The July 2017 submission presented a cost-minimisation analysis of nicotine lozenges/gum versus nicotine patches. The tables below summarise the recalculated ex-manufacturer prices for the nicotine lozenges and gum according to the revised equi-effective doses for high or moderate nicotine dependence.

Table 2: Cost minimisation calculations for the high nicotine dependent group

	Patch 21mg/24hr	Lozenge 4mg	Gum 4mg
Pack Size	28	216	216
Equi-effective doses (12 weeks therapy)	84	588	560
Ex-Manufacturer Price (12 weeks therapy)	\$117.42	\$117.42	\$117.42
Number of packs (12 weeks therapy)	3	2.7	2.6
Cost neutral packs (12 weeks therapy)	N/A	3	3
Wastage (= cost neutral – equi-effective)	N/A	60	88
Approved Ex-Manufacturer Price (AEMP)	\$39.14	\$39.14	\$39.14
Maximum Quantity	1	1	1
Dispensed Price Maximum Quantity (DPMQ)	\$53.17	\$53.17	\$53.17
Number of repeats	2	2	2

Source: Calculated during the evaluation

Table 3: Cost minimisation calculations for the moderate nicotine dependent group

	Patch 14mg/24hr	Lozenge 2mg	Gum 2mg
Pack Size	28	216	216
Equi-effective doses (12 weeks therapy)	84	588	840
Ex-Manufacturer Price (12 weeks therapy)	\$117.42	\$117.42	\$117.42
Number of packs (12 weeks therapy)	3	2.7	3.9
Cost neutral packs (12 weeks therapy)	N/A	3	4
Wastage (= cost neutral – equi-effective)	N/A	60	24
Approved Ex-Manufacturer Price (AEMP)	\$39.14	\$39.14	\$29.36
Maximum Quantity	1	1	2
Dispensed Price Maximum Quantity (DPMQ)	\$53.17	\$53.17	\$74.23
Number of repeats	2	2	1

Source: Calculated during the evaluation

- 3.2 PBAC noted that both the nicotine gum and lozenge results in some wastage, due to;
- the available pack sizes for the nicotine gum and lozenge; and
 - the requirement to maintain a cost neutral approach against the nicotine patch.
- 3.3 The 2mg nicotine gum is the only exception as one prescription equals 6 weeks of therapy with only one allowable repeat. This approach minimises excessive wastage for this product and in addition maintains 12 weeks of overall therapy.

4 PBAC Outcome

- 4.1 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.
- 4.2 The PBAC re affirmed that it was reasonable for nicotine patches to be considered the main comparator for nicotine gum and lozenges in the monotherapy setting.
- 4.3 The PBAC considered that a substantial number of uncertainties with the approach taken by the submission to calculate the equi-effective doses were suitably addressed in the revised calculations. The PBAC therefore supported the revised equi-effective doses in Table 1.
- 4.4 The financial implications of listing the gum and lozenges were considered in the July 2017 consideration. That submission used a non-standard market share approach based on a combination of the potential shift from the over-the-counter (OTC) lozenge and gum markets and from the existing PBS listed therapies (nicotine patches, varenicline and bupropion) to the proposed nicotine gum and lozenges.

- 4.5 Overall, the DUSC previously considered that the financial estimates were likely to be underestimated with a high degree of uncertainty. The PBAC noted that no further information was available to address this uncertainty.
- 4.6 In its July 2017 consideration 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 treatment.
- 4.7 Acknowledging that smoking cessation was a public health priority area and that it was willing to consider an alternative approach for the subsidisation of NRT products, the PBAC considered that further clinical evidence and utilisation estimates were warranted before the comparative efficacy and cost-effectiveness of combination use could be appropriately determined by the Committee.
- 4.8 The PBAC acknowledged that the use of nicotine gum and lozenges as monotherapies (as is the case for nicotine patches subsidised through the PBS) is not consistent with the latest clinical guidelines², which encourage health professionals to consider recommending the use of combination NRT. However in the absence of evidence about the cost-effectiveness of combination treatment the PBAC reiterated that it is not possible to further an assessment of combination treatment at the present time in the context of this submission.
- 4.9 The PBAC considered that a broader review of PBS-subsidised nicotine dependence treatments in the context of the current clinical guidelines would however be informative to whether current subsidy arrangements could better achieve the intended purpose of supporting smoking cessation.
- 4.10 The PBAC noted that nicotine gum and lozenges could be used in combination with other PBS-subsidised NRTs, and agreed that this risk could be mitigated through requiring in the restriction that treatment with either the gum or lozenge or patch be the sole PBS-subsidised therapy for nicotine dependence.
- 4.11 The PBAC noted that this submission is not eligible for an Independent Review because it has received a positive recommendation.

Outcome:

Recommended

5 Recommended listing

Add new items:

² <http://www.racgp.org.au/your-practice/guidelines/smoking-cessation/>

Public Summary Document – March 2018 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
NICOTINE				
Gum 2mg, 216	2	1	Nicotinell®	Orion Laboratories Pty Ltd
Gum 4 mg, 216	1	2		
Lozenge 2 mg, 216	1	2		
Lozenge 4 mg, 216	1	2		

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Nicotine dependence
PBS Indication:	Nicotine dependence
Restriction:	<input checked="" type="checkbox"/> Restricted benefit
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.
Prescriber Instructions	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.
Administrative Advice	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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Condition:	Nicotine dependence
PBS Indication:	Nicotine dependence

Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required - Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	The treatment must be the sole PBS-subsidised therapy for this condition.
Population criteria:	Patient must be an Aboriginal or a Torres Strait Islander person
Note:	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.
Administrative Advice:	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised.

6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

7 Sponsor's Comment

The sponsor had no comment.