

**7.11 INSULIN DEGLUDEC WITH INSULIN ASPART,
Injections, cartridges, 70 units-30 units per mL,
3 mL, 5
Injections, pre-filled pen, 70 units-30 units per mL,
3 mL, 5
Ryzodeg[®], Novo Nordisk Pharmaceuticals Pty Ltd**

1 Purpose of Application

- 1.1 The minor resubmission requested an unrestricted listing for insulin degludec with insulin aspart (IDegAsp) for treatment of adult patients with diabetes mellitus where insulin treatment is necessary.
- 1.2 The minor resubmission sought to address issues raised in the November 2017 PBAC consideration of the previous major submission.

For more detail on PBAC's view, see section 6 PBAC outcome.

2 Requested listing

- 2.1 The requested PBS listing was unchanged from the previous submission. Suggestions and additions proposed by the Secretariat to the requested listing are added in italics.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
INSULIN DEGLUDEC + INSULIN ASPART				
Insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL cartridge	5	1	\$ [REDACTED] (Published) \$ [REDACTED] (Effective)	Ryzodeg [®] Penfill [®] Novo Nordisk Pharmaceuticals Pty Limited
Insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL syringes	5	1	\$ [REDACTED] (Published) \$ [REDACTED] (Effective)	Ryzodeg [®] FlexTouch [®]

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> <i>Medical Practitioners</i> <input checked="" type="checkbox"/> <i>Nurse practitioners</i> <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> <i>Unrestricted</i> <input 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
Administrative Advice	<i>Special Pricing Arrangements apply</i>

For more detail on PBAC's view, see section 6 PBAC outcome.

3 Background

- 3.1 IDegAsp was TGA registered for the improvement of glycaemic control in adult patients with diabetes mellitus requiring basal and prandial insulin in November 2017.
- 3.2 IDegAsp was previously considered by the PBAC at the November 2017 PBAC meeting. The PBAC did not recommend IDegAsp for treatment of adult patients with diabetes mellitus where insulin treatment is necessary on the basis that the cost-effectiveness of the drug in type 2 diabetes mellitus (T2DM) was not established at the proposed price, and because the clinical place in therapy for type 1 diabetes mellitus (T1DM) was not established in the submission.
- 3.3 A summary of the outstanding matters of concern to the PBAC from the November 2017 consideration are provided in Table 1.

Table 1: PBAC matters of concern in previous consideration (November 2017)

Matters of concern	How the resubmission addresses it
<p>Regulatory status The PBAC noted that IDegAsp was not TGA registered at the time of its consideration. The PBAC also noted that IDeg as a single agent is currently undergoing TGA evaluation. (PBAC PSD, November 2017, item 7.3)</p>	<p>IDegAsp was registered on the Australian Register of Therapeutic Goods (ARTG) on 29 November 2017 (p 5 of the resubmission, TGA ARTG website).</p>
<p>DPMQ The submission proposed a special price arrangement (SPA) with an effective dispensed price of \$[REDACTED]. The requested published dispensed price is \$429.93. (PBAC PSD, November 2017, item 2.1)</p>	<p>The effective (confidential) price of IDegAsp has been revised downwards to DPMQ \$[REDACTED] to take into account the lower cost-minimised price versus BIAsp, which represents a [REDACTED]% reduction to the price proposed in the July 2017 submission. The list (published) price has also been revised in this minor submission to \$[REDACTED], which is lower than the list price of IGar and IDet. The Sponsor proposes a SPA with the list price and lower effective prices detailed below, and is willing to work with the Department to offer a condition to rebate the Government up-front (subject to appropriate reconciliation measures).</p>
<p>Comparator <u>T2DM</u>: The PBAC considered that biphasic insulin aspart 30 (BIAsp 30) was an appropriate comparator in T2DM. However, the PBAC noted that the price requested for IDegAsp was higher than that for insulin glargine (IGlar) and that a clinical comparison against IGlar in T2DM may be informative in this context. (PBAC PSD, November 2017, item 7.5)</p>	<p>In regards to the suggested comparison with IGlar, the Sponsor clarifies that the revised price in this minor submission is lower than the listed and effective price of IGlar (p 5 of the resubmission).</p>
<p><u>T1DM</u>: The PBAC considered that insulin detemir (IDet) was not the appropriate comparator in T1DM. The PBAC considered that BIAsp 30 or other pre-mixed insulins may be more appropriate comparators as they possess pharmacologic similarities. (PBAC PSD, November 2017, item 7.6)</p>	<p>IDet is removed as a cost comparator in the cost-minimisation analysis. Considering the potential benefit of IDegAsp in the T1DM population, the Sponsor is offering a price equivalent to BIAsp 30 in the T1DM population (p 5 of the resubmission).</p>

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<p>Clinical claim – safety The PBAC considered that while IDegAsp was statistically superior in terms of number of biochemically confirmed hypoglycaemic episodes in some trials, this difference may not be clinically meaningful, particularly as there was no difference in the relative risk of an individual patient having at least one confirmed hypoglycaemic event and there was no difference in the risk of a patient having a severe hypoglycaemic event (either relative risk or incidence rate ratios). Thus the PBAC did not accept the submission’s claim of superior safety. (PBAC PSD, November 2017, item 6.23)</p>	<p>The Sponsor maintains that IDegAsp provides important therapeutic benefits to patients in minimising the risk of hypoglycaemia, which is supported by the statistically lower number of biochemically confirmed hypoglycaemic episodes. However, in this minor resubmission, the cost offset associated with hypoglycaemia has been removed and no claim for reduced hypoglycaemia benefit is made in the modelled CMA. The Sponsor acknowledges that ‘there was no difference in the relative risk of an individual patient having at least one confirmed hypoglycaemic event and there was no difference in the risk of a patient having a severe hypoglycaemic event’ as stated in the Minutes. (p 7 of the resubmission).</p>
<p>The submission presented a cost-minimisation analysis of IDegAsp versus BIAsp 30 (T2DM) and IDet (T1DM), with cost offsets for severe hypoglycaemic events. The PBAC noted the submission’s approach was in line with the clinical evidence of non-inferior efficacy in T2DM, but not in line with the clinical evidence for safety. (PBAC PSD, November 2017, item 6.24)</p>	<p>The cost offset associated with hypoglycaemia has been removed and no claim for reduced hypoglycaemia benefit is made in the modelled CMA against BIAsp 30 in the resubmission. (p 7 of the resubmission).</p>
<p>Equi-effective dose The PBAC noted the submission proposed the equi-effective doses for IDegAsp compared to BIAsp 30 in T2DM to be different for insulin-naïve (1:1) and insulin-experienced (0.84:1) patients (weighted equi-effective dose is ██████, assuming ██████% insulin naïve and ██████% insulin experienced patients (submission table 3.1.2 p 64)). The submission postulated that this is “related to the glucose lowering profile of IDegAsp, in which the rapid acting prandial effect is followed by a distinct separate and stable basal effect” (p62). Although the ESC considered that the approach used in the submission which resulted in different equi-effective doses was reasonable, the PBAC considered that the differences in naïve and experienced patients created some uncertainty in the equi-effective dose overall. (PBAC PSD, November 2017, item 6.30)</p>	<p>The equi-effective doses were estimated from the mean total daily insulin dose at 26 weeks in T2DM trials and remain unchanged from the previous submission:</p> <ul style="list-style-type: none"> • Insulin-naïve T2DM (IDegAsp vs BIAsp 30) = 1 unit : 1 unit (total insulin); • Insulin-experienced T2DM (IDegAsp vs BIAsp 30) = 0.84 units : 1 unit (total insulin). <p>(pp 10-11 of the resubmission).</p>
<p>Financial estimates The PBAC considered there was a high degree of uncertainty in the financial estimates (see paragraph 6.41). The PBAC noted that at the proposed price, the listing of IDegAsp would result in a higher cost to the PBS/RPBS due to the higher price of IDegAsp compared to the insulins replaced and because the cost offsets included in the price calculations are not included in the financial estimates. (PBAC PSD, November 2017, item 7.12)</p>	<p>Resubmission presented a reduced cost-minimised price that accounts for the following updates in the economic model:</p> <ul style="list-style-type: none"> • removal of the cost-offset due to hypoglycaemia events; • removal of IDet as a cost comparator and offer a price equivalent to BIAsp 30 in the T1DM population. The proposed price is based on a weighted price across T1DM and T2DM. In T2DM, the cost-minimising price is calculated using the dose relativity between IDegAsp and BIAsp 30 in the clinical trials; • as proposed in the pre-PBAC response (Oct 2017), include premixed neutral/isophane human insulin (the cheapest premixed insulin) as a cost comparator, with a weight of 17% (human insulin share of the premixed insulin market) in the premixed insulin price calculation; • use approved ex-manufacturer prices (AEMP) to work out the cost-minimising price of IDegAsp. <p>The model structure and other inputs remain unchanged from the previous submission. The economic analysis is a weighted CMA across T1DM, insulin-naïve T2DM, insulin-</p>

	experienced T2DM populations, which aligns with the clinical evidence presented in the July 2017 submission. The drug costs and expected savings with IDegAsp due to lower insulin doses in T2DM are incorporated in the analysis. (pp 9-10 of the resubmission).
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Source: Compiled during the evaluation. Paragraph references refer to the November 2017 IDegAsp ratified minutes.

For more detail on PBAC's view, see section 6 PBAC outcome

4 Comparator

T2DM

- 4.1 The previous major submission considered by the PBAC in November 2017 nominated BIAsp 30 as the comparator in the T2DM population. BIAsp 30 was accepted by the PBAC as an appropriate comparator in the T2DM population and remains unchanged in this resubmission.

T1DM

- 4.2 The previous major submission considered by the PBAC in November 2017 nominated IDet as the comparator in the T1DM patient population. The PBAC considered that IDet was not the appropriate comparator in T1DM. The PBAC considered that BIAsp 30 or other pre-mixed insulins may be more appropriate comparators as they possess pharmacologic similarities.
- 4.3 The resubmission removed IDet as a comparator in the cost-minimisation analysis and nominated BIAsp 30 as the comparator in the T1DM population. The PBAC considered that this was appropriate.

For more detail on PBAC's view, see section 6 PBAC outcome.

5 Current situation

Sponsor hearing

- 5.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 5.2 The PBAC noted that no consumer comments were received for this item.

Clinical trials and clinical claim

- 5.3 As a minor submission, no new clinical trials were presented in the resubmission.
- 5.4 In November 2017, the PBAC considered that the claim of non-inferior comparative effectiveness was reasonably supported by the data for T2DM (paragraph 7.8, IDegAsp PSD November 2017 PBAC meeting). The November 2017 submission presented results for the primary outcome (change in HbA1c) from five direct

randomised trials. The PBAC noted that the results of the four trials, excluding the extension trial (study 3645), were in agreement with the predetermined non-inferiority margin proposed. The proposed drug was non-inferior for all the analysed trials with a non-inferiority margin of 0.4%. None of the trials showed superiority for change in HbA1c (paragraph 6.11, IDegAsp PSD November 2017 PBAC meeting).

- 5.5 In November 2017, the PBAC considered that the claim of superior comparative safety was not adequately supported by the data (paragraph 7.9, IDegAsp PSD November 2017 PBAC meeting). While IDegAsp was statistically superior in terms of number of biochemically confirmed hypoglycaemic episodes, this difference may not be clinically meaningful, particularly as there was no difference in the relative risk of an individual patient having at least one confirmed hypoglycaemic event and there was no difference in the risk of a patient having a severe hypoglycaemic event (either relative risk or incidence rate ratios; paragraph 6.23, IDegAsp PSD November 2017 PBAC meeting). The minor submission maintained that there was evidence that IDegAsp has clinical benefit in minimising the risk of hypoglycaemia. However, the cost offset associated with reduced hypoglycaemia was removed and no claim for reduced hypoglycaemia benefit was made in the modelled CMA in the minor resubmission. The PBAC considered that the changes made to the model in the minor resubmission were acceptable.

Economic analysis

- 5.6 The following economic issues were addressed in the minor resubmission:
- In the previous submission, a CMA against BIAsp 30 (T2DM) and IDet (T1DM) was presented. As the PBAC did not accept IDet an appropriate comparator, the resubmission removed IDet as a comparator in the CMA and proposed a price weighted across T1DM and T2DM in comparison to BIAsp 30. The cost-minimised price was also calculated using the dose relativity between IDegAsp and BIAsp 30 in T2DM the clinical trials as in the major submission.
 - In November 2017 the PBAC considered the inclusion of cost offsets for severe hypoglycaemic events in the price for IDegAsp to be inconsistent with the clinical evidence for safety (paragraph 7.10 of November 2017 IDegAsp PSD). Therefore, the resubmission removed the cost offsets due to the hypoglycaemic events.
 - The PBAC considered that the differences in insulin naïve and experienced patients in T2DM created some uncertainty in the equi-effective dose overall. The resubmission stated that the differences are due to the different ways the populations are clinically managed.
 - Approved ex-manufacturer prices (AEMP) were used to calculate the cost-minimised price of IDegAsp.
- 5.7 The resubmission did not alter the economic model structure, population weight, or equi-effective doses from that considered by the PBAC in November 2017.

5.8 The proposed equi effective doses are:

- Insulin-naïve T2DM (IDegAsp vs BIAsp 30) = 1 unit : 1 unit (total insulin);
- Insulin-experienced T2DM (IDegAsp vs BIAsp 30) = 0.84 units : 1 unit (total insulin);
- T1DM: The submission stated that an equi-effective dose in the T1DM population is not used in the economic analysis in the resubmission and that a price equivalent to BIAsp 30 is proposed. This infers a relativity of 1:1.

5.9 The revised price for IDegAsp calculated in T2DM is AEMP (maximum quantity) \$ [REDACTED]. The costs per unit for other insulins included in the CMA are also presented in Table 2.

Table 2: Calculation of insulin costs per unit

PBS item	Max qty packs	No. of repeats	AEMP (Max qty)	Total Insulin units	Price (AEMP) per unit
Cost-minimising price of IDegAsp in T2DM	5	1	\$ [REDACTED]	7,500	\$ [REDACTED]
PBS item 8609D Insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection (100 units/mL in total)	5	1	\$211.90	7,500	\$0.028
PBS item 9040T Insulin detemir 100 units/mL injection	5	1	\$ [REDACTED] ^a	7,500	\$ [REDACTED]
PBS item 8435Y Insulin aspart 100 units/mL injection	5	1	\$211.90	7,500	\$0.028
PBS item 1763T Insulin neutral 30 units/mL + insulin isophane (70 units) per mL, 3 mL, 5 injection	5	1	\$176.60	7,500	\$0.024

Source: Table 3.3 (p12) of minor submission

Max qty, maximum quantity; AEMP, approved ex-manufacturer price

Notes: ^aConfidential effective price. The price of IDet is not used in the base case analysis.

5.10 The minor resubmission claimed that IDegAsp is cost neutral to BIAsp 30 in the T2DM population with a calculated cost-minimising price AEMP \$ [REDACTED]/maximum quantity. Table 3 summarises the insulin use and incremental costs for the IDegAsp in T2DM.

Table 3: Cost-minimisation analysis (AEMP) for IDegAsp vs BIAsp 30 in T2DM

	T2DM insulin-naïve patients ([REDACTED]%)			T2DM insulin-experienced patients ([REDACTED]%)			Total T2DM patients
	IDegAsp	BIAsp 30	Diff.	IDegAsp	BIAsp 30	Diff.	Diff.
Insulin units per year	[REDACTED]	27,010	[REDACTED]	[REDACTED]	31,498	[REDACTED]	[REDACTED]
Insulin cost per year	\$ [REDACTED]	\$742	\$ [REDACTED]	\$ [REDACTED]	\$865	-\$ [REDACTED]	\$ [REDACTED]

IDegAsp, insulin degludec/insulin aspart (Ryzodeg® 70/30); BIAsp, biphasic insulin aspart 30; Diff, difference; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus.

Source: Attach_3_Ryzodeg_Section 3_Dec 2017 minor submission.xlsx, Table 3.4 of minor resubmission (p12)

5.11 The proposed price was based on a weighted price across T1DM and T2DM population in comparison to BIAsp 30. The weighted price is AEMP \$ [REDACTED]/pack as

presented in Table 4. The premium over BIAsp 30 was reduced from █% in the previous submission to █% at the AEMP and the effective AEMP is █% lower than IGlAr.

Table 4: Weighted price calculation (AEMP) across all diabetes patients

Patient group	Proportion (Table 3.1)	AEMP/Max Qty	AEMP/pack
T2DM	█%	\$█	\$█
T1DM	█%	\$█	\$█
All diabetes patients	100%	$90.3\% \times \$█ + 9.7\% \times \$█ = \$█$	\$█

Source: Table 3.5 of minor resubmission (p12)

5.12 The resubmission proposed a price reduction to the requested special pricing arrangement (SPA) with an effective dispensed price of \$█ and a published dispensed price of \$█. This is approximately █% reduction from the previous submission which proposed an SPA with an effective dispensed price of \$█ and published dispensed price of \$█.

Estimated PBS usage & financial implications

5.13 The previous submission used a market share approach to estimate the extent of IDegAsp use for the diabetes treatment. This remained unchanged in the resubmission. The following were updated in the financial estimates of the resubmission:

- The revised price of IDegAsp, reduced from DPMQ \$█ to \$█;
- The confidential price for IGlAr and IDet were revised slightly to align with the prices provided in November 2017 PBAC PSD (Table 2, p4);
- The resubmission noted the ESC/PBAC’s comments regarding substitution rates, and these were adjusted, with ±10% variations in the sensitivity analyses.

5.14 The revised net financial implications of the proposed PBS listing are presented in Table 5.

Table 5: Dispensed units and net financial implications to PBS/RPBS of listing IDegAsp

	Year 1 (2018)	Year 2 (2019)	Year 3 (2020)	Year 4 (2021)	Year 5 (2022)	Year 6 (2023)
Dispensed units of IDegAsp						
PBS	██████	██████	██████	██████	██████	██████
RPBS	██████	██████	██████	██████	██████	██████
Total cost of IDegAsp						
PBS cost (inc. copayments)	██████	██████	██████	██████	██████	██████
PBS cost to government (excl. copayments)	██████	██████	██████	██████	██████	██████
RPBS cost (inc. copayments)	██████	██████	██████	██████	██████	██████
RPBS cost to government (excl. copayments)	██████	██████	██████	██████	██████	██████
Net cost saving for other medications						
PBS cost (inc. copayments)	██████	██████	██████	██████	██████	██████
PBS cost to government (excl. copayments)	██████	██████	██████	██████	██████	██████
RPBS cost (inc. copayments)	██████	██████	██████	██████	██████	██████
RPBS cost to government (excl. copayments)	██████	██████	██████	██████	██████	██████
Overall net total cost of IDegAsp						
PBS cost (inc. copayments)	██████	██████	██████	██████	██████	██████
PBS cost to government (excl. copayments)	██████	██████	██████	██████	██████	██████
RPBS cost (inc. copayments)	██████	██████	██████	██████	██████	██████
RPBS cost to government (excl. copayments)	██████	██████	██████	██████	██████	██████
Net cost to PBS + RPBS (excl. copayments)	██████	██████	██████	██████	██████	██████

PBS, Pharmaceutical Benefits Scheme; RPBS, Repatriation Pharmaceutical Benefits Scheme

Source: Attachment 4_Ryzodeg_Section 4_Dec 2017 minor submission.xlsx, Table 4.1 of minor resubmission (pp13-14)

5.15 The net cost to the PBS was expected to be less than \$10 million in year 1, increasing to less than \$10 million in Year 6. The cost to government was reduced from the previous submission, which was driven by the reduced price offered in this submission. The small remaining cost to Government is driven by the difference in dose relativities.

Financial management

5.16 While not a matter for the PBAC to consider, in addition to the SPA proposed, the minor resubmission proposed that the Sponsor was willing to work with the Department to offer a condition to rebate the Government up-front (subject to appropriate reconciliation measures); thus instead of paying the rebate after all

pharmacy transactions are collected, the Sponsor would pay the rebate in advance and reconcile to the actual movements later.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of insulin degludec with insulin aspart (IDegAsp) as an unrestricted benefit on the basis of cost-minimisation to biphasic insulin aspart 30 (BIAsp 30) for the treatment of diabetes mellitus.
- 6.2 The PBAC considered an unrestricted listing was appropriate for IDegAsp as it would be consistent with other insulins on the PBS, with the exception of IDet and insulin bovine.
- 6.3 The PBAC noted that IDegAsp was TGA registered for the improvement of glycaemic control in adult patients with diabetes mellitus requiring basal and prandial insulin in November 2017.
- 6.4 The PBAC considered that BIAsp 30 was the appropriate the comparator in both the T1DM and T2DM populations.
- 6.5 The PBAC noted that no new clinical trials were presented in the resubmission. The PBAC also noted that it had previously accepted that the claim of non-inferior comparative effectiveness was reasonably supported by the data for T2DM (paragraph 7.8, IDegAsp PSD November 2017).
- 6.6 The PBAC accepted the equi-effective doses in the T1DM and T2DM populations proposed in the resubmission of:
 - Insulin-naïve T2DM (IDegAsp vs BIAsp 30) = 1 unit : 1 unit (total insulin);
 - Insulin-experienced T2DM (IDegAsp vs BIAsp 30) = 0.84 units : 1 unit (total insulin);
 - T1DM (IDegAsp vs BIAsp 30) = 1 unit : 1 unit (total insulin).
- 6.7 The PBAC noted that no benefit claim for reduced hypoglycaemia was made in the modelled cost-minimisation analysis in the resubmission, on the basis that the PBAC had previously advised that the cost offset associated with reduced hypoglycaemia should be removed from the economic model. In addition, the PBAC considered that the remaining uncertainties were addressed by the proposed reduction in price for IDegAsp in the resubmission.
- 6.8 The PBAC considered the updated financial estimates in the resubmission to be reasonable.
- 6.9 The PBAC recommended the Early Supply Rule should not apply to the listing of IDegAsp, to be consistent with the listings for other insulins on the PBS.
- 6.10 The PBC advised that IDegAsp is suitable for prescribing by nurse practitioners as other insulins are currently included for prescribing by nurse practitioners within

collaborative arrangements.

- 6.11 The PBAC advised that, under Section 101(3BA) of the *National Health Act 1953*, insulin degludec + insulin aspart should not be treated as interchangeable on an individual patient basis with any other drug or medical preparation.
- 6.12 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
INSULIN DEGLUDEC + INSULIN ASPART				
Insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL cartridge	5	1	Ryzodeg® Penfill®	Novo Nordisk Pharmaceuticals Pty Limited
Insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL syringes	5	1	Ryzodeg® FlexTouch®	

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> <i>Medical Practitioners</i> <input checked="" type="checkbox"/> <i>Nurse practitioners</i> <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> <i>Unrestricted</i> <input 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
Administrative Advice	<i>Special Pricing Arrangements apply</i>

8 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.

9 Sponsor’s Comment

The sponsor had no comment.