

6.11 LACOSAMIDE
tablet, 50 mg;
Vimpat®; UCB Australia Pty Ltd.

1 Purpose of Application

- 1.1 Lacosamide 50 mg is currently listed on the PBS for intractable partial epileptic seizures for titration purposes only. The minor submission requested to list the 50mg strength for maintenance treatment for a small number of patients to be able to be maintained on the lowest dose which controls their condition.

2 Requested listing

- 2.1 Lacosamide 50 mg pack of 14 tablets is currently available for initial treatment on the PBS for titration purposes only. The 100 mg and 150 mg strengths of lacosamide are available as packs of 14 for titration purposes, as well as packs of 56 for initial and continuing treatment.

- 2.2 The minor submission requested to list the 50 mg strength pack of 14 tablets for continuation treatment with either:

- a listing for continuation for 56 tablets (ie 4 x 14 packs), with the number of repeats the same as the other strengths, i.e., 56 tablets with 5 repeats; or
- a listing continuation for the current 14 pack, but allowing for greater than 1 repeat.

The sponsor assumed that the first of these options is the most practical.

3 Background

- 3.1 The PBAC had previously considered several submissions for lacosamide.

- 3.2 In November 2009, the PBAC recommended listing lacosamide as an Authority Required benefit for treatment, initiated by a neurologist, in combination with two or more anti-epileptic drugs (AEDs) which includes one second-line adjunctive agent, of partial epileptic seizures which are not controlled satisfactorily by other AEDs in a patient aged 16 years or older with intractable epilepsy.

- 3.3 In November 2011, the PBAC rejected a submission seeking an Authority Required (STREAMLINED) listing and to extend the current PBS listing to include the treatment, in combination with a non-sodium channel target AED, of a patient with partial epileptic seizures which are not controlled satisfactorily by other AEDs (i.e. second line treatment).

- 3.4 In November 2012, the PBAC recommended a submission to amend the continuing restriction to allow prescribers to introduce lacosamide in combination with two other AEDs and then to remove the concurrent AEDs as a matter of clinically judgement, while maintaining the existing risk-share arrangement. The PBAC also recommended streamlining the Authority Required indication.

Public Summary Document – March 2015 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
LACOSAMIDE Tablet 50 mg, 14	4	5	\$ [REDACTED]	Vimpat® UCB Australia Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Intractable partial epileptic seizures
PBS Indication:	Intractable partial epileptic seizures
Treatment phase:	Continuing
Restriction Level / Method:	<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 checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have previously been treated with PBS-subsidised lacosamide.
Population criteria:	Patient must be aged 16 years or older

Clinical trials

- 3.5 As a minor submission, no new clinical trials were presented in the submission.
- 3.6 The basis of the minor submission’s request was:
- a quality use of medicines (QUM) issue for a small number of patients, in that patients should be able to be maintained on the lowest dose of lacosamide that controls their condition; and
 - patient safety reasons, to avoid patients being advised by clinicians to cut the 100 mg tablet in half to obtain the required 50 mg dose.

Economic analysis

- 3.7 As a minor submission, no economic comparison was presented.

Estimated PBS usage & financial implications

- 3.8 The minor submission estimated there to be very little, if any, financial implications to the PBS and also suggest that the listing may result in a small decrease in script approval and processing time.
- 3.9 The submission proposed no change to the ex-manufacturer price (AEMP) of the 50 mg 14 tablet pack in seeking a listing of 56 tablets.

4 PBAC Outcome

- 4.1 The PBAC recommended the listing of lacosamide, 50mg strength for continuation treatment for 56 tablets (ie 4 x 14 packs), with the five repeats, consistent with the other strengths of lacosamide.
- 4.2 The PBAC agreed that it would be appropriate for patients to be maintained on the lowest dose that effectively controls their condition.
- 4.3 The PBAC considered that this change would not alter current PBS utilisation and expenditure on lacosamide.
- 4.4 The PBAC recommended that lacosamide be listed for PBS prescribing by nurse practitioners as continuing therapy only.
- 4.5 The PBAC recommended that the Safety Net 20 Day Rule should not apply, as it does to other listings for lacosamide.
- 4.6 The PBAC noted that this submission is not eligible for an Independent Review, as it resulted in a positive recommendation.

Outcome:
Recommended

5 Recommended listing

5.1 Amend maximum quantity and/or number of repeats as follows:

Name, Restriction, Manner of administration and Qty form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
LACOSAMIDE Tablet 50 mg, 14	4	5	Vimpat® UCB Australia Pty Ltd

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:	Intractable partial epileptic seizures
PBS Indication:	Intractable partial epileptic seizures
Treatment phase:	Continuing

Restriction Level / Method:	<input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have previously been treated with PBS-subsidised lacosamide.
Population criteria:	Patient must be aged 16 years or older

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.