

6.11 LENVATINIB

Capsule, 4 mg (as mesilate)

Capsule, 10 mg (as mesilate)

Lenvima[®], Eisai Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested an amendment to the current PBS listing of lenvatinib to allow for prescribing of one pack of 10 mg and two packs of 4 mg capsules.

2 Requested listing

- 2.1 The submission requested a change to the current listing as shown below in italics, and suggested deletions are crossed out with strikethrough.

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Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	DPMQ	Proprietary Name and Manufacturer
LENVATINIB lenvatinib 4 mg capsule, 30	1	2	\$3,304.52	Lenvima® Eisai Australia
lenvatinib 10 mg capsule, 30	2	2	\$6,459.53	

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
Severity:	Locally advanced or metastatic
Condition:	Differentiated thyroid cancer
PBS Indication:	Locally advanced or metastatic differentiated thyroid cancer
Treatment phase:	Initial treatment
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 symptomatic progressive disease prior to treatment; OR Patient must have progressive disease at critical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures AND Patient must have TSH adequately repressed [TSH ≤0.50 µIU/mL] AND Patient must have a WHO performance status of 2 or less AND Patient must be one in whom surgery is inappropriate AND Patient must not be a candidate for radiotherapy with curative intent AND The condition must be refractory to radioactive iodine. AND The treatment must be the sole PBS-subsidised therapy for this condition.
Prescriber Instructions:	Radioactive iodine refractory is defined as: - A lesion without iodine uptake on a radioactive iodine (RAI) scan, or - Receiving cumulative RAI ≥ 600 mCi, or - Experiencing a progression after a RAI treatment within 12 months of enrolment, or - After two RAI treatments within 12 months of each other
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. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

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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
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PBS Indication:	Locally advanced or metastatic differentiated thyroid cancer
Treatment phase:	Continuing treatment
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 issued with an authority prescription for this drug for this condition AND Patient must have stable or responding disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) AND The treatment must be the sole PBS-subsidised therapy for this condition.
Administrative Advice:	Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows: Complete response (CR) is disappearance of all target lesions. Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions. Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions. Stable disease (SD) is small changes that do not meet above criteria. No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

For more detail on PBAC’s view, see section 5 PBAC outcome.

3 Background

- 3.1 At the July 2016 meeting, the PBAC recommended the listing of lenvatinib for the treatment of locally advanced or metastatic differentiated thyroid cancer based on acceptable cost effectiveness over best supportive care.
- 3.2 The sponsor stated that over the past 12 months a number of treating clinicians have made contact to request a listing amendment that would allow for easier prescribing of doses that differed from the recommended starting dose of 24 mg per day. The submission reports that a dose reduction from 24 mg per day occurs in up to 80% of patients, and this is a common mechanism for managing treatment related side effects.
- 3.3 The sponsor requested that the current PBS listing of lenvatinib be amended to create two additional item codes to allow for prescribing of one pack of 10 mg and two packs of 4 mg capsules.
- 3.4 The Secretariat noted that it may be more appropriate to retain the current maximum quantity for the 4 mg table, but remove the administrative advice that states “no increase in the maximum quantity or the number of units may be

authorised”. The small number of patients taking an 8 mg dose will then be able to access one months’ supply via an authority request.

- 3.5 Prescribers may administratively change the number of packs prescribed, so that they may prescribe one pack of 10 mg capsules.

For more detail on PBAC’s view, see section 5 PBAC outcome.

4 Consideration of the evidence

Sponsor hearing

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

Consumer comments

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

Clinical trials

- 4.3 As a minor submission, no clinical trials were presented in the submission.

Estimated PBS usage & financial implications

- 4.4 The minor submission claimed that the suggested changes would result in a cost-saving to the PBS/RPBS and would allow prescribers to accurately prescribe all approved doses and combinations of the 10 mg and 4 mg strength capsules in monthly allocations, reducing wastage.
- 4.5 The submission also claimed that there would also be reduced potential for wasted 10 mg packs when dose interruptions, changes or cessation of therapy occur.
- 4.6 The submission did not present financial estimates of the cost saving.

5 PBAC Outcome

- 5.1 The PBAC recommended an amendment to the general schedule Authority Required (STREAMLINED) listing for lenvatinib (Lenvima®) for the treatment of locally advanced or metastatic differentiated thyroid cancer, to allow for prescribing of one pack of 10 mg and two packs of 4 mg capsules.
- 5.2 The PBAC, noting the advice from the secretariat, considered that this amendment should occur by removing the administrative advice stating, “no increase in the maximum quantity or the number of units may be authorised” in the current lenvatinib restriction, rather than by the addition of new item codes. The PBAC noted that this would allow patients taking an 8 mg dose to access one months’ supply via an authority request.
- 5.3 The PBAC noted that this submission is not eligible for an Independent Review because the PBAC has made a positive recommendation.

Outcome:

Recommended

6 Recommended listing

6.1 Amend existing/recommended listing as follows:

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7 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.

8 Sponsor's Comment

The sponsor had no comment.