

7.22 THYROXINE (as sodium) 25 microgram tablet, 200 Eltroxin®, Aspen Pharma Pty Ltd

1 Purpose of Application

- 1.1 The minor resubmission requested an Unrestricted benefit listing for thyroxine (as sodium) 25 micrograms.

2 Requested listing

- 2.1 The submission requested the following new listing:

Name, Restriction, Manner of administration and form	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer	
THYROXINE thyroxine sodium 25 microgram tablet, 200 200		1	Eltroxin	Aspen Pharma 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
Restriction Level / Method:	Unrestricted
Administrative Advice	Eltroxin is not interchangeable with Oroxine or Eutroxsig on a dose-to-dose basis, and dose titration may be required. Continuing therapy only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicines for, a patient has been initiated by a medical practitioner. Further information can be found in the explanatory notes for nurse practitioners.

- 2.2 The proposed ex-manufacturer price for thyroxine sodium 25 microgram, 200 tablets was \$ [REDACTED].

3 Background

- 3.1 Thyroxine sodium 25 microgram has been previously considered by the PBAC at its November 2015 meeting. At the meeting, the PBAC recommended the listing of five strengths (50, 75, 100, 125 and 200 microgram) of Eltroxin as an Unrestricted benefit. The PBAC did not recommend the listing of the 25 microgram strength, as it was not considered a clinically necessary dose.
- 3.2 Thyroxine sodium (also known as levothyroxine sodium) is TGA registered for:
- the management of demonstrated thyroid hormone deficiency

- suppressing thyrotropin (TSH) for the management of TSH-responsive tumours of the thyroid

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 and welcomed the input from the Sydney Children's Hospital Network via the Consumer Comments facility on the PBS website. Their comment described the perceived benefits of the 25 microgram tablet, including particularly neonates, post-discharge. The comment stated that paediatric patients often need small doses of thyroxine (i.e. less than 50 micrograms), that the accuracy of splitting a 50 microgram tablet outside of the healthcare setting is questionable, and that splitting it is a burden for the patient's family.

Submission

- 4.3 The resubmission claimed that "a dose of 25 microgram or 12.5 microgram is recommended as an initiation dose for elderly patients, for those patients with ischaemic heart disease, and for children, as it is recognized that an accurate dose is important to reduce the risk of unacceptable adverse effects." The resubmission claimed that thyroxine 25 microgram tablets will likely be used in a small population.
- 4.4 The resubmission included an article from the Australian Prescriber (2008;31:159-61), which states, "Elderly patients and those with known heart disease should start with a daily dose of thyroxine 25 microgram for 3-4 weeks with a reassessment of their condition before further increments of 25 microgram every 3-4 weeks until the predicted dose is reached."
- 4.5 The resubmission included a letter from a clinician supporting the introduction of a 25 microgram dose. Supporting reasons included variable dosages dependent on patient characteristics, lack of appropriate dosage of the thyroxine medication, and need for more precision in getting optimal dosage in severe clinical situations, such as in elderly, very young and pregnant patients.

For more detail on PBAC's view, see section 5 "PBAC outcome"

5 PBAC Outcome

- 5.1 The PBAC decided not to recommend thyroxine (as sodium) 25 microgram for PBS-listing. In making its recommendation, the PBAC considered that thyroxine 25 microgram tablets would not be cost-effective at the price proposed by the submission, noting that there were several strengths of thyroxine already listed or recommended for listing on the PBS (including 50, 75, 100, 125 and 200

micrograms). The PBAC did not accept that there was an unmet clinical need for this new presentation.

5.2 The PBAC considered that given the range of different strengths of thyroxine that the PBAC has previously recommended for PBS listing, the availability of a new presentation would not address any unmet clinical need. The PBAC considered that if the sponsor wished to make a resubmission, a pragmatic way forward would be to price the 25 microgram strength at a cost proportional to the other recommended strengths, noting that if the 25 microgram strength were to be used in practice, it would most likely be used in addition to other strengths for titration purposes.

5.3 The PBAC noted that this submission is eligible for an Independent Review.

Outcome:

Rejected

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.