

**5.19 PEMETREXED
1 g injection, 1 vial,
PEMETREXED MYX®, Mayne Pharma International Pty Ltd**

1 Purpose of Application

- 1.1 The minor submission requested PBS listing of an additional 1 g strength of pemetrexed (as disodium). The currently listed strengths are 100 mg and 500 mg.

2 Requested listing

- 2.1 The submission sought to list the 1 g strength on the PBS with the same Section 100 – Efficient Funding of Chemotherapy (public/private) listing as the existing strengths.

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

3 Background

- 3.1 PEMETREXED MYX is TGA registered for:
- treatment of patients with malignant pleural mesothelioma, in combination with cisplatin;
 - treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in combination with cisplatin; and
 - monotherapy is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology after prior platinum-based chemotherapy.
- 3.2 The 1 g strength was registered on the ARTG on 28 May 2015.

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 Lung Foundation Australia via the Consumer Comments facility on the PBS website. The Lung Cancer Foundation Australia recommended that lung cancer patients receive early access to any treatments for which the evidence shows benefit.

Clinical trials

- 4.3 The basis of the minor submission's request was TGA approval of the 1 g strength. The TGA letter of registration noted that PEMETREXED MYX could be considered bioequivalent to AMLITA powder for injection (Eli Lilly Australia Pty Limited). The submission provided third party compounding data suggesting the usage of pemetrexed is as follows:
- 500-1000 mg, 70%
 - 1000mg exactly, 20%
 - 1000-1100mg, 6%
 - 1100 mg exactly, 2%
 - <500mg, 2%

Economic analysis

- 4.4 The submission requested an ex-manufacturer price of \$3,119.70, in line with the same price per mg as the 100 mg and 500 mg vials currently listed on the PBS.

Estimated PBS usage & financial implications

- 4.5 The minor submission estimated there to be no financial implications to the PBS.

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

5 PBAC outcome

- 5.1 The PBAC recommended listing the 1g strength of pemetrexed under the same circumstances and based on a same (ex-manufacturer) price per mg as the currently listed strengths of pemetrexed.
- 5.2 The PBAC noted that the use of a 1 g vial would involve less processing than the use of multiple smaller vials. The PBAC noted that there may be wastage concerns with a larger vial size, but considered that this risk would be mitigated under Efficient Funding of Chemotherapy arrangements.
- 5.3 The PBAC noted that pemetrexed should be exempt from the Early Supply Rule as it currently does not apply to Section 100 Efficient Funding of Chemotherapy listings.
- 5.4 The PBAC recommended that pemetrexed should not be treated as interchangeable on an individual patient basis with any other drug(s) or medicinal formulation(s).
- 5.5 The PBAC advised that pemetrexed is not suitable for prescribing by nurse practitioners.

Outcome:

Recommended

6 Recommended listing

6.1 Add new items:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
PEMETREXED 1 g injection, 1 vial	1	5	PEMETREXED MYX	Mayne Pharma

Category / Program	Chemotherapy (public/private)
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
PBS Indication:	Locally advanced or metastatic non-small cell lung cancer
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 received prior treatment with platinum-based chemotherapy
Prescriber Instructions	The patient's body surface area (BSA) must be documented in the patient's medical records at the time the treatment cycle is initiated Doses greater than 500 mg per metre squared BSA are not PBS-subsidised

Category / Program	Chemotherapy (public/private)
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
PBS Indication:	Mesothelioma
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:	The treatment must be in combination with cisplatin
Prescriber Instructions	The patient's body surface area (BSA) must be documented in the patient's medical records at the time the treatment cycle is initiated Doses greater than 500 mg per metre squared BSA are not PBS-subsidised

7 Context for Decision

Public Summary Document – March 2016 PBAC Meeting

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.