

5.20 PEMETREXED,

Solution concentrate for I.V. infusion 100 mg in 4 mL vial,

Solution concentrate for I.V. infusion 500 mg in 20mL vial,

Solution concentrate for I.V. infusion 1000 mg in 40mL vial,

**Pemetrexed Ever Pharma[®],
Interpharma Pty Ltd**

1 Purpose of Submission

- 1.1 The Committee Secretariat submission requested a Section 100 Efficient Funding of Chemotherapy (EFC) Program listing of three new forms of pemetrexed 100 mg/4 mL, 500 mg/20 mL and 1000 mg/40 mL ready to use (RTU) solutions for injection (herein referred to as Pemetrexed Ever Pharma[®]) under the same circumstances as the currently listed brands of pemetrexed powder for I.V. infusion.

2 Background

- 2.1 Pemetrexed is currently listed on the Pharmaceutical Benefits Scheme (PBS) as an unrestricted benefit listing. The currently listed strengths are 100 mg, 500 mg and 1000 mg.
- 2.2 EFC medicines are governed by the National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011 and subsection 33(2) allows substitution of brands with the same chemotherapy drug.
- 2.3 The Product Information states that pemetrexed can be administered via intravenous infusion only.

Registration status

- 2.4 Pemetrexed Ever Pharma was registered on the Australian Register of Therapeutic Goods on 25 October 2022 for the same indications as the currently PBS-listed pemetrexed brands.

Previous PBAC consideration

- 2.5 Pemetrexed Ever Pharm has not been previously considered by the Pharmaceutical Benefits Advisory Committee (PBAC).

- 2.6 At its July 2018 meeting, the PBAC noted the requests from the Medical Oncology Group of Australia to amend a number of PBS listings for oncology-related listings. With regards to pemetrexed, PBAC noted the price of pemetrexed had dropped substantially in the past several years and recommended amending the listings of pemetrexed to an unrestricted benefit. The unrestricted listing was implemented in July 2019.

3 Requested listing

- 3.1 The submission requested the following new listings

Add new medicinal products as follows:

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	No. of Rpts	DPMA
PEMETREXED Injection	4600D (Public)	1100 mg	5	\$188.23 (Public)
	7255W (Private)			\$231.27 (Private)
Available brands				
Pemetrexed (Ever Pharma) pemetrexed 100 mg/4 mL injection, 4 mL vial pemetrexed 500 mg/20 mL injection, 20 mL vial pemetrexed 1000mg/40 mL injection, 40 mL vial				
Pemetrexed APOTEX (pemetrexed 500 mg injection, 1 vial)				
Pemetrexed Accord (pemetrexed 1 g injection, 1 vial) (pemetrexed 100 mg injection, 1 vial) (pemetrexed 500 mg injection, 1 vial)				
Pemetrexed SUN (pemetrexed 1 g injection, 1 vial) (pemetrexed 100 mg injection, 1 vial) (pemetrexed 500 mg injection, 1 vial)				
Pemetrexed-AFT (pemetrexed 100 mg injection, 1 vial) (pemetrexed 500 mg injection, 1 vial)				
Tevatrexed [This brand was delisted from 1 March 2023.] (pemetrexed 100 mg injection, 1 vial) (pemetrexed 500 mg injection, 1 vial)				
Benefit type: Unrestricted benefit				
Category / Program: Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals				
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				

- 3.2 The submission requested Pemetrexed Ever Pharma to be a streamlined benefit listing. The submission also requested the target PBS population and disease state for Pemetrexed Ever Pharma be the same as the existing listed strengths of pemetrexed and specifically listed the following indications:

- Patients with malignant pleural mesothelioma

- Patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.

Given the existing listed strengths of pemetrexed are listed as unrestricted benefits, Pemetrexed Ever Pharma® will be listed as unrestricted benefits, if recommended.

The submission also explained that listing of Pemetrexed Ever Pharma® is not anticipated to alter the current clinical treatment algorithm, other than to offer efficient administration of pemetrexed to patients due to the lack of need of mixing of powder into a solution.

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

4 Comparator

- 4.1 The submission nominated pemetrexed 100 mg, 500 mg and 1000 mg powders for injections as the main comparator. This was appropriate.
- 4.2 The TGA considered Pemetrexed Ever Pharma to be bioequivalent to one of the previously PBS-listed brands of pemetrexed powder for injection (ALIMTA®).

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

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item.

Consumer comments

- 5.2 The PBAC welcomed the input from organisations (1) via the Consumer Comments facility on the PBS website. The PBAC noted the consumer comment received from Lung Foundation Australia supporting listing of new forms of pemetrexed and describing a range of benefits including greater access to treatment options for patients.

Estimated PBS utilisation and financial implications

- 5.3 The submission used a market-share approach to estimate there would be nil financial impact of the requested listing. The submission stated that the proposed listing was not expected to impact the overall market size for pemetrexed.
- 5.4 The submission estimated that 25% of patients currently using the 100 mg, 500 mg and 1000 mg powders for injection would switch to Pemetrexed Ever Pharma. No evidence was provided to support this assumption.
- 5.5 The submission requested listing the three new forms of pemetrexed solution for injection at the same corresponding price as the currently listed powder for injection forms of pemetrexed.

- 5.6 The submission estimated that the requested listings will not result in a net cost to the PBS.

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

6 PBAC Outcome

- 6.1 The PBAC recommended the Section 100 EFC program listing of three new forms of pemetrexed (Pemetrexed Ever Pharma) 100 mg/4 mL, 500 mg/20 mL and 1000 mg/40 mL solutions for injection as unrestricted benefits under the same circumstances as the currently listed brands of pemetrexed powder for I.V. infusion.
- 6.2 The PBAC noted that the derived price of pemetrexed 100 mg/4 mL, 500 mg/20 mL and 1000 mg/40 mL solutions for injection was consistent with the other strengths of pemetrexed and considered this was appropriate.
- 6.3 The PBAC considered the estimates for PBS utilisation and financial impact were reasonable and noted that the proposed listing is expected to have nil cost to Government.
- 6.4 The PBAC noted that EFC medicines are governed by the National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011 and that Section 33(1) allows the supplier of the chemotherapy pharmaceutical benefit to use the same chemotherapy drug but a different form to make the infusion, meaning the three new forms of pemetrexed (Pemetrexed Ever Pharma®) 100 mg/4 mL, 500 mg/20 mL and 1000 mg/40 mL solutions for injection may be substituted for the existing forms.
- 6.5 The PBAC noted that its recommendation was on a cost-minimisation basis and advertised that, because pemetrexed solutions for injection are not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the currently listed forms of pemetrexed, or not expected to address a high urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.
- 6.6 The PBAC advised that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add three new medicinal product packs as follows:

Public Summary Document – March 2023 PBAC Meeting

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	No. of Rpts	DPMA
PEMETREXED Injection	4600D (Public) 7255W (Private)	1100 mg	5	\$188.23 (Public) \$231.27 (Private)
Available brands				
Pemetrexed APOTEX (pemetrexed 500 mg injection, 1 vial)				
Pemetrexed Accord (pemetrexed 1 g injection, 1 vial) (pemetrexed 100 mg injection, 1 vial) (pemetrexed 500 mg injection, 1 vial)				
Pemetrexed SUN (pemetrexed 1 g injection, 1 vial) (pemetrexed 100 mg injection, 1 vial) (pemetrexed 500 mg injection, 1 vial)				
Pemetrexed-AFT (pemetrexed 100 mg injection, 1 vial) (pemetrexed 500 mg injection, 1 vial)				
Pemetrexed (Ever Pharma) (pemetrexed 100 mg/4 mL injection, 4 mL vial) (pemetrexed 500 mg/20 mL injection, 20 mL vial) (pemetrexed 1 g /40 mL injection, 40 mL vial)				
Benefit type: Unrestricted benefit				
Category / Program: Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals				
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.