

**5.20 CABAZITAXEL,  
Injection concentrate for I.V. infusion 60 mg in 6 mL,  
Cabazitaxel Ever Pharma<sup>®</sup>,  
Interpharma Pty Ltd**

**1 Purpose of Application**

- 1.1 The minor submission requested Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of a new form of cabazitaxel (concentrated solution for injection) for the treatment of patients with castration resistant metastatic carcinoma of the prostate.
- 1.2 The submission requested listing under the same conditions as Jevtana, the currently listed brand of cabazitaxel.

**2 Background**

- 2.1 Cabazitaxel was first TGA registered on 8 December 2011 for use in combination with prednisone or prednisolone for the treatment of patients with metastatic castration resistant prostate cancer previously treated with a docetaxel containing regimen. Cabazitaxel Ever Pharma was TGA registered on 27 October 2020 for the same indication.
- 2.2 Cabazitaxel is currently listed on the PBS as an Authority Required (STREAMLINED) listing for castration resistant metastatic carcinoma of the prostate.

**3 Requested listing**

- 3.1 The submission requested that Cabazitaxel Ever Pharma be listed under the same restriction criteria as Jevtana (4376H, 7236W). The submission proposed no changes to the existing restriction.

Public Summary Document– March 2021 PBAC Meeting

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	No. of Rpts	Manufacturer
CABAZITAXEL Injection		55 mg	5	Interpharma Pty Ltd
<b>Available brands</b>				
Jevtana (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (& inert substance diluent [4.5 mL vial], 1 pack)	4376H 7236W			Sanofi-aventis Australia Pty Ltd
Cabazitaxel (Ever Pharma) (cabazitaxel 60 mg/ 6 mL injection vial, 6 mL vial)	NEW (Public) NEW (Private)			Interpharma Pty Ltd
<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals				
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required – Streamlined [4662]				
<b>Episodicity:</b>				
<b>Severity:</b> Castration resistant metastatic				
<b>Condition:</b> carcinoma of the prostate				
<b>Indication:</b> Castration resistant metastatic carcinoma of the prostate				
<b>Clinical criteria:</b>				
The treatment must be in combination with prednisone or prednisolone				
<b>AND</b>				
<b>Clinical criteria:</b>				
The treatment must not be used in combination with abiraterone				
<b>AND</b>				
<b>Clinical criteria:</b>				
Patient must have a WHO performance status of 2 or less				
<b>AND</b>				
<b>Clinical criteria:</b>				
Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel				

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

## 4 Comparator

- 4.1 The submission nominated the currently listed brand of the same drug, Jevtana, as the comparator.

## 5 Consideration of evidence

### *Sponsor hearings*

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

### *Consumer comments*

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

### *Clinical trials*

- 5.3 There were no clinical trials presented in the submission

- 5.4 The basis of the submission's request was that Cabazitaxel Ever Pharma was developed as a generic formulation of Jevtana which the TGA considered bioequivalent to Jevtana.

### ***Clinical claim***

- 5.5 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of Cabazitaxel Ever Pharma (solution concentrate for injection) compared with Jevtana (powder for injection). The PBAC considered this appropriate.

### ***Estimated PBS usage & financial implications***

- 5.6 While not a matter for the PBAC, listing of a new bioequivalent form of cabazitaxel would trigger a 25% statutory price reduction under s99ACB of the *National Health Act 1953*. The drug cabazitaxel would also move into the F2 formulary and be subject to price disclosure.
- 5.7 The submission proposed DPMAs of \$2,262.23 (Private Hospital) and \$2,201.84 (Public Hospital) which were calculated based on a 25% reduction to the published DPMAs for Jevtana at the time of submission. Jevtana was subject to a Special Pricing Arrangement (SPA) at the time of submission, however, as of 1 February 2021, Jevtana was no longer subject to the SPA and the price of cabazitaxel in the Schedule was reduced.
- 5.8 The statutory price reduction is applied to the AEMP. Based on the current AEMP for Jevtana (cabazitaxel, concentrated injection 60 mg (as acetone solvate) in 1.5 mL, with diluent) of \$1,261.54, application of a 25% statutory price reduction would result in an AEMP of \$946.16. The pre-PBAC Response acknowledged that the AEMP for cabazitaxel would be lower than initially determined by the sponsor if Cabazitaxel Ever Pharma was PBS-listed.
- 5.9 The submission did not provide estimated financial implications to the PBS as the submission expected Cabazitaxel Ever Pharma to only substitute for Jevtana, and both products would have the same price.

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

## **6 PBAC Outcome**

- 6.1 The PBAC recommended the listing of Cabazitaxel Ever Pharma for the treatment of patients with castration resistant metastatic carcinoma of the prostate, under the same conditions as Jevtana, the currently listed cabazitaxel brand, on the basis it should be available only under special arrangements under Section 100 (Efficient Funding of Chemotherapy).
- 6.2 The PBAC recommended listing Cabazitaxel Ever Pharma on a cost-minimisation basis to Jevtana. The PBAC noted the listing of Cabazitaxel Ever Pharma is expected to result in no net cost to the Government because it is not expected to grow the market.

- 6.3 The PBAC noted that the TGA considered Cabazitaxel Ever Pharma to be bioequivalent to Jevtana.
- 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(2) allows substitution of brands under the same item code.
- 6.5 The PBAC noted that the Early Supply Rule does not currently apply to Section 100 (Efficient Funding of Chemotherapy) listings.
- 6.6 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that because cabazitaxel is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over cabazitaxel, or not expected to address a high and 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.
- 6.7 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

**Outcome:**

Recommended

## **7 Recommended listing**

- 7.1 Add new medicinal product pack (60 mg/6 mL injection vial, 6 mL vial) and trade product/non-originator available brand (Cabazitaxel Ever Pharma) as follows:

Public Summary Document– March 2021 PBAC Meeting

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	No. of Rpts
CABAZITAXEL Injection	4376H (Public) 7236W (Private)	55 mg	5
<b>Available brands</b>			
Jevtana (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (& inert substance diluent [4.5 mL vial], 1 pack)			
Cabazitaxel (Ever Pharma) (cabazitaxel 60 mg/6 mL injection vial, 6 mL vial)			
<b>Restriction Summary 11223 / Treatment of Concept: 4662</b> (as of 1 March 2021)			
<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners			
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required – (STREAMLINED) [4662]			
<b>Indication:</b> Castration resistant metastatic carcinoma of the prostate			
<b>Clinical criteria:</b>			
The treatment must be in combination with prednisone or prednisolone			
<b>AND</b>			
<b>Clinical criteria:</b>			
The treatment must not be used in combination with abiraterone			
<b>AND</b>			
<b>Clinical criteria:</b>			
Patient must have failed treatment with docetaxel due to resistance or intolerance			
<b>AND</b>			
<b>Clinical criteria:</b>			
Patient must have a WHO performance status of 2 or less			
<b>AND</b>			
<b>Clinical criteria:</b>			
Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel			

***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.