

5.24 CABAZITAXEL, Solution concentrate for I.V. infusion 60 mg in 3 mL, Cabazitaxel Accord®, Accord Healthcare Pty. Ltd.

1 Purpose of Submission

- 1.1 The Committee Secretariat submission sought a Section 100 Efficient Funding of Chemotherapy (EFC) Program, Authority Required (STREAMLINED) listing of a new vial size containing 60 mg in 3 mL cabazitaxel, Cabazitaxel Accord®, under the same circumstances as the currently listed brands of cabazitaxel for treatment of castration resistant metastatic carcinoma of the prostate.

2 Background

Registration status

- 2.1 Cabazitaxel Accord was Therapeutic Goods Administration (TGA) registered on 3 August 2021 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.
- 2.2 Cabazitaxel Accord has the same indications as the currently listed brands of cabazitaxel including Jevtana®, Cabazitaxel Ever Pharma® and Cabazitaxel Juno®.

Current status

- 2.3 The concentration and dilution instructions for Cabazitaxel Accord (solution concentrate for I.V. infusion 60 mg in 3 mL) are different to those for Jevtana and Cabazitaxel Juno (Concentrated injection 60 mg in 1.5 mL, with diluent) and to those for Cabazitaxel Ever Pharma (solution concentrate for I.V. infusion 60 mg in 6 mL).
- 2.4 EFC medicines are governed by the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* and subsection 33(1) allows the supplier of the infusion to use pharmaceutical benefits with the same chemotherapy drug but a different form to make the infusion, meaning different forms may be substituted.

Previous PBAC consideration

- 2.5 Jevtana was recommended as a Section 100 (EFC) listing as an Authority Required (Private Hospital/Clinic) and an Authority Required (STREAMLINED) (Public Hospital) listing in March 2012.

- 2.6 In March 2021 the Pharmaceutical Benefits Advisory Committee (PBAC) recommended listing Cabazitaxel Ever Pharma under the same circumstances as Jevtana.

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

3 Requested listing

- 3.1 The submission requested the following:

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Add new medicinal product as follows:

Name, Restriction, Manner of administration and form	PBS item code	Max. Amount	No. of Rpts	Manufacturer
CABAZITAXEL Injection	4376H 7236W	55 mg	5	Accord Healthcare Pty Ltd
Available brands				
Cabazitaxel Ever Pharma (cabazitaxel 60 mg/6 mL injection, 6 mL vial)				
Cabazitaxel Juno (cabazitaxel 60 mg/1.5 mL injection, [1.5 mL vial] (& inert substance diluent [4.5 mL vial], 1 pack)				
Jevtana (cabazitaxel 60 mg/1.5 mL injection, [1.5 mL vial] (& inert substance diluent [4.5 mL vial], 1 pack)				
Cabazitaxel Accord (cabazitaxel 60 mg/3 mL injection, 3 mL vial)				
Category / Program: Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals				
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
Restriction type: <input checked="" type="checkbox"/> Authority Required – Streamlined [4662]				
Episodicity:				
Severity: Castration resistant metastatic				
Condition: carcinoma of the prostate				
Indication: Castration resistant metastatic carcinoma of the prostate				
Clinical criteria:				
The treatment must be in combination with prednisone or prednisolone				
AND				
Clinical criteria:				
Patient must have failed treatment with docetaxel due to resistance or intolerance The condition must be resistant to treatment with docetaxel, OR				
Patient must have a documented intolerance necessitating permanent treatment withdrawal or a contraindication to docetaxel				
AND				
Clinical criteria:				
The treatment must not be used in combination with abiraterone				
AND				
Clinical criteria:				
Patient must have a WHO performance status of 2 or less				
AND				
Clinical criteria:				
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 sponsor nominated the following comparators for Cabazitaxel Accord: Jevtana, Cabazitaxel Ever Pharma and Cabazitaxel Juno. This was appropriate.

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 noted that no consumer comments were received for this item.

Clinical claim

- 5.3 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of Cabazitaxel Accord compared with Jevtana.
- 5.4 The PBAC considered that the claim of non-inferior comparative effectiveness was reasonable.
- 5.5 The PBAC considered that the claim of non-inferior comparative safety was reasonable.

Estimated PBS utilisation and financial implications

- 5.6 The sponsor has requested the same approved ex-manufacturer price (AEMP) (\$946.16) for Cabazitaxel Accord as Cabazitaxel Ever Pharma, Cabazitaxel Juno and Jevtana. Cabazitaxel is scheduled to take a price disclosure reduction on 1 April 2022 with the AEMP reducing from \$946.16 to \$595.32.
- 5.7 The sponsor requested the same price as the listed brands of cabazitaxel and there are no variations in dosing. The DPMA as of January 2022 for cabazitaxel is \$1,032.44 (Public Hospital, Pharmaceutical Benefits Scheme (PBS) code 4376H) and \$1,086.72 (Private Hospital, PBS code 7236W). The DPMA from 1 April 2022, following the price disclosure reduction, will be \$681.60 (Public Hospital, PBS code 4376H) and \$730.96 (Private Hospital, PBS code 7236W).
- 5.8 The submission did not include any financial estimates.
- 5.9 The submission stated that listing Cabazitaxel Accord on the PBS will not lead to any adverse financial effect on the PBS. This claim is appropriate as the listing of Cabazitaxel Accord is not expected to have any financial impact.

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

6 PBAC Outcome

- 6.1 The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) listing of a new form of cabazitaxel, solution concentrate for I.V. infusion 60 mg in 3 mL (Cabazitaxel Accord®) under the same circumstances as the currently listed brands of cabazitaxel for treatment of castration resistant metastatic carcinoma of the prostate.
- 6.2 The PBAC noted that EFC medicines are governed by the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* and subsection 33(1) allows the supplier of the infusion to use pharmaceutical benefits with the same chemotherapy drug but a different form to make the infusion, meaning different forms may be substituted.
- 6.3 The PBAC noted that the listing of Cabazitaxel Accord is not expected to have any financial impact on the PBS.
- 6.4 The PBAC recommended updating the existing restriction for cabazitaxel to improve clarity by replacing 'Patient must have failed treatment with docetaxel due to resistance or intolerance' with:

'The condition must be resistant to treatment with docetaxel, OR

Patient must have a documented intolerance necessitating permanent treatment withdrawal or a contraindication to docetaxel'.
- 6.5 The PBAC recommended updating the existing restriction for cabazitaxel to improve clarity by replacing 'The treatment must not be used in combination with abiraterone' with:

'The treatment must not be used in combination with a novel hormonal drug' with the administrative note 'Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide'.
- 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 the currently listed 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.

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Outcome:
Recommended

7 Recommended listing

7.1 Add new item and amend existing listing as follows:

Name, Restriction, Manner of administration and form	PBS item code	Max. Amount	No. of Rpts	Manufacturer
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Available brands				
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Jevtana (cabazitaxel 60 mg/1.5 mL injection, [1.5 mL vial] (& inert substance diluent [4.5 mL vial], 1 pack)				
Cabazitaxel Accord (cabazitaxel 60 mg/3 mL injection, 3 mL vial)				
Category / Program: Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals				
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Clinical criteria:				
The treatment must be in combination with prednisone or prednisolone				
AND				
Clinical criteria:				
Patient must have failed treatment with docetaxel due to resistance or intolerance The condition must be resistant to treatment with docetaxel, OR				
Patient must have a documented intolerance necessitating permanent treatment withdrawal or a contraindication to docetaxel				
AND				
Clinical criteria:				
The treatment must not be used in combination with a novel hormonal drug				
AND				
Clinical criteria:				
Patient must have a WHO performance status of 2 or less				
AND				
Clinical criteria:				
Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel				
NOTE: Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.				

Flow-on changes:

- 7.2 Update clinical criteria for current cabazitaxel PBS-listed items (Jevtana, Cabazitaxel Ever Pharma, Cabazitaxel Juno):
- replace 'Patient must have failed treatment with docetaxel due to resistance or intolerance' with '*The condition must be resistant to treatment with docetaxel, OR Patient must have a documented intolerance necessitating permanent treatment withdrawal or a contraindication to docetaxel*'
 - replace 'The treatment must not be used in combination with abiraterone' with 'The treatment must not be used in combination with a novel hormonal drug'
 - add the following administrative note: Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide'.

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.