

5.13 PACLITAXEL, NANOPARTICLE ALBUMIN-BOUND Powder for I.V. injection containing 250 mg paclitaxel, Abraxane[®], Specialised Therapeutics Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission requested a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for an additional 250 mg strength of nanoparticle albumin-bound paclitaxel (*nab*-paclitaxel) and a price increase for *nab*-paclitaxel use in pancreatic cancer.

2 Requested listing

- 2.1 The submission requested the 250 mg vial to be listed for the same indication and under the same conditions as the currently listed *nab*-paclitaxel 100 mg vial. The sponsor did not request restriction changes.

3 Background

- 3.1 *Nab*-paclitaxel 100 mg is TGA registered for:
- in combination with gemcitabine, the first-line treatment of patients with metastatic adenocarcinoma of the pancreas.
 - the treatment of metastatic carcinoma of the breast after failure of anthracycline therapy.
 - in combination with carboplatin, the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation
- 3.2 *Nab*-paclitaxel was recommended by the PBAC at its March 2014 meeting for the treatment of metastatic (stage IV) adenocarcinoma of the pancreas in combination with gemcitabine. The PBAC considered that the 100 mg vial should be available only under special arrangements under Section 100 – Efficient Funding of Chemotherapy. The PBAC was satisfied that *nab*-paclitaxel in combination with gemcitabine provides, for some patients, a significant improvement in efficacy over gemcitabine monotherapy. The PBAC had not previously considered *nab*-paclitaxel for this indication.
- 3.3 The PBAC noted at the March 2014 meeting that the 250 mg vial of *nab*-paclitaxel was not yet TGA registered, and considered that the absence of the 250 mg vial may increase wastage.

- 3.4 *Nab*-paclitaxel 100 mg vial was listed on 1 November 2014 for Stage IV (metastatic) adenocarcinoma of the pancreas.
- 3.5 A minor submission was submitted to the November 2018 PBAC meeting seeking a price increase for use in pancreatic cancer and reimbursement of a 250 mg vial presentation. However, the 250 mg vial presentation was concurrently under TGA evaluation for registration and a Delegate’s overview was not available at the time of submission. The sponsor was notified that the TGA/PBAC parallel process was not available for minor submissions and therefore the submission proceeded to the November 2018 meeting for consideration of the price increase request only.
- 3.6 At its November 2018 Meeting, the PBAC did not recommend the request for an increase in the price of *nab*-paclitaxel for use in pancreatic cancer as the submission did not provide an adequate justification for a price increase. The PBAC noted the Department’s advice that the sponsor has the option of approaching the Department to change or remove its special pricing arrangement as such arrangements are put in place at the request of the sponsor. The PBAC further noted that removing the special pricing arrangement would remove the rebate, thus resolving the issue described by the sponsor.
- 3.7 The 250 mg vial of *nab*-paclitaxel was approved by the TGA on 27 November 2018 for the same indication as 100 mg vial.
- 3.8 In this minor submission, the sponsor requested a price increase based only on the reduction of wastage due to the availability of the 250 mg vial. The sponsor stated that the cost per patient would remain the same.

Current situation

- 3.9 The current Deed of Agreement for *nab*-paclitaxel includes a special pricing arrangement consisting of a [REDACTED] % rebate.
- 3.10 The submission requested an increase in the effective dispensed price for maximum amount (DPMA) for the 100 mg vial to \$ [REDACTED] (private) and \$ [REDACTED] (public). The requested price for the 250 mg vial is \$ [REDACTED] (private) and \$ [REDACTED] (public). The submission stated that listing of the 250 mg vial would reduce wastage, using the September 2017 DUSC report as evidence presented in Table 1 below.

Table 1: Vials and wastage of Abraxane with and without a 250 mg vial listed (pancreatic cancer)

	Year	2014	2015	2016	2017
With 100 mg vial	Vials	3,909	35,618	36,929	38,404
	Wastage (mg)	65,422	596,274	667,018	668,472
With 100 mg and 250 mg vials	100 mg vials	2,026	20,630	21,130	22,140
	250 mg vials	650	5212	5519	5,612
	Wastage (mg)	39,622	400,474	466,868	445,072
Wastage difference (mg)		25,800	195,800	200,150	223,400

Source: Minor submission page 4. Adapted from Table 10 of September 2017 DUSC Report

Note 2017 data were extracted from DUSC report and annualised, rather than extracting actual sales data from the PBS website and calculating dosing and wastage by methods that may not match that used for previous years.

3.11 The Sponsor stated that the current submission did not include wastage due to vial sharing in the scope of the submission however; guidance was requested regarding the Efficient Funding of Chemotherapy process. The Secretariat noted that the process of the Efficient Funding of Chemotherapy is outside of the scope of the PBAC.

3.12 The submission did not provide any additional evidence or basis for the requested price increase.

For more detail on PBAC's view, see section 7 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 that no consumer comments were received for this item.

Economic analysis

4.3 The submission did not present an economic analysis.

Estimated PBS usage & financial implications

4.4 The minor submission presented estimates based on data from the September 2017 DUSC report that the sponsor stated differs from the Medicare usage report. The sponsor claims that the uptake of *nab*-paclitaxel has been lower than forecast, therefore the financial implication was calculated based on the known usage and a linear forecast was applied for the forthcoming years.

Table 2: Estimated financial implications of price change

Year	2019	2020	2021	2022
PBS Scripts (Medicare Data)				
Vials (DUSC)				
Calculations based on PBS Scripts (Medicare Data)				
PBS/RPBS Benefit				
PBS Benefit (Medicare Data)				
Calculations based on Vials Dispensed (DUSC)				
Cost to PBS/RPBS				
Cost to PBS (current effective price)	\$	\$	\$	\$
Cost to PBS (current published price)	\$	\$	\$	\$
Cost to PBS (proposed new price)	\$	\$	\$	\$
PBS/RPBS Benefit				
PBS Benefit (current effective price)	\$	\$	\$	\$
PBS Benefit (current published price)	\$	\$	\$	\$
PBS Benefit (proposed new price)	\$	\$	\$	\$

The redacted table shows that at Year 4, the estimated number of vials was 10,000 to 50,000 and the net cost to the PBS/RPBS would be \$10 to \$20 million.

For more detail on PBAC’s view, see section 7 PBAC outcome.

5 PBAC Outcome

- 5.1 The PBAC recommended the listing of a 250 mg vial of nanoparticle albumin-bound paclitaxel (*nab*-paclitaxel) powder for injection under the same conditions as the currently listed *nab*-paclitaxel 100 mg vial. The PBAC did not recommend a price increase for *nab*-paclitaxel use in pancreatic cancer.
- 5.2 The PBAC recommended the 250 mg vial at an equivalent price per mg to the existing 100 mg vial for its corresponding indications. The PBAC noted that since there should be no increase in patient numbers or the cost for each patient, the 250 mg vial listing should not increase overall cost to the Government.
- 5.3 The PBAC recalled that it had not recommended the request for a price increase for *nab*-paclitaxel for use in pancreatic cancer at its November 2018 meeting, based on inadequate justification provided in the sponsor’s submission.
- 5.4 The PBAC recalled that at its March 2014 meeting, it had considered that *nab*-paclitaxel would not be cost effective at the base case ICER of \$45,000 to \$75,000/LYS, and that an ICER in the vicinity of \$15,000 to \$45,000/LYS would be appropriate. The PBAC considered that the price negotiated by the sponsor at the time of listing *nab*-paclitaxel for pancreatic cancer placed it at the higher end of an appropriate cost-effectiveness range. It was uncertain whether *nab*-paclitaxel would still be cost-effective for this indication at a higher price. The PBAC also noted that at the time of its March 2014 recommendation, a sensitivity analysis in which the 250 mg vial was

not available showed an increased ICER compared to the base case. The PBAC considered that listing of the 250 mg vial did not warrant a price increase, but may provide some assurance that the pancreatic cancer listing is cost effective.

- 5.5 The PBAC recommended that the wording of the restriction be the same as for the currently listed 100 mg vial.
- 5.6 The PBAC advised, under Section 101 3BA of the *National Health Act*, that *nab-paclitaxel* should not be treated as interchangeable on an individual patient basis with any other drug(s) or medicinal preparation(s).
- 5.7 The PBAC advised that *nab-paclitaxel* is not suitable for prescribing by nurse practitioners.
- 5.8 The PBAC recommended that the Early Supply Rule should not apply.
- 5.9 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

6.1 Add new item:

Name, Restriction, Manner of administration and form	Max. amount	No. of Rpts	Proprietary Name and Manufacturer	
PACLITAXEL, NANOPARTICLE ALBUMIN-BOUND, Powder for I.V. injection containing 250 mg paclitaxel	275 mg	11	Abraxane	Specialised Therapeutics Pty Ltd

Category / Program	Section 100 – Efficient funding of Chemotherapy
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:	Stage IV (metastatic) adenocarcinoma of the pancreas
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 gemcitabine AND The condition must not have been treated previously with PBS-subsidised therapy AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less

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Prescriber Instructions	A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
Administrative Advice	Not for use as neoadjuvant or adjuvant therapy

Name, Restriction, Manner of administration and form	Max. amount	No. of Rpts	Proprietary Name and Manufacturer	
PACLITAXEL, NANOPARTICLE ALBUMIN-BOUND, Powder for I.V. injection containing 250 mg paclitaxel	580 mg	5	Abraxane	Specialised Therapeutics Pty Ltd

Category / Program	Section 100 – Efficient funding of Chemotherapy
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:	Metastatic breast 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

Name, Restriction, Manner of administration and form	Max. amount	No. of Rpts	Proprietary Name and Manufacturer	
PACLITAXEL, NANOPARTICLE ALBUMIN-BOUND, Powder for I.V. injection containing 250 mg paclitaxel	580 mg	5	Abraxane	Specialised Therapeutics Pty Ltd

Category / Program	Section 100 – Efficient funding of Chemotherapy
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:	HER2 positive breast 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

7 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.

8 Sponsor's Comment

The sponsor had no comment.