Nanoparticle albumin-bound paclitaxel for pancreatic cancer: 24 month predicted versus actual analysis

Drug utilisation sub-committee (DUSC)

September 2017

Abstract

Purpose

To compare the predicted and actual utilisation of nanoparticle albumin-bound paclitaxel (nab-paclitaxel) for stage IV (metastatic) adenocarcinoma of the pancreas in the first 24 months of PBS listing. Nab-paclitaxel was PBS listed for this indication on 1 November 2014.

Restriction

Stage IV (metastatic) adenocarcinoma of the pancreas. The treatment must be in combination with gemcitabine, and the condition must not have been treated previously with PBS-subsidised therapy, and the patient must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Data Source / methodology

Prescription claim data for nab-paclitaxel for adenocarcinoma of the pancreas were extracted from November 2014 to March 2017.

Key Findings

- Since listing, 3,284 patients have been supplied nab-paclitaxel for adenocarcinoma of the pancreas.
- In 2016 1,221 patients initiated therapy and 1,708 patients were treated.
- The number of treated patients per year is similar to expected, but the number of prescriptions (treatments) and vials was lower than predicted. The main reasons for this difference may be PBS patients requiring a delay in the next dose and dose reducing more than patients in the trial which was used to inform the estimates of use.

Purpose of analysis

To compare the predicted and actual utilisation of nanoparticle albumin-bound paclitaxel (nab-paclitaxel) for Stage IV (metastatic) adenocarcinoma of the pancreas in the first 24 months of PBS listing.

Background

Clinical situation

Pancreatic adenocarcinoma is a tumour that begins in the exocrine cells of the pancreas. Exocrine pancreatic cancer is the most common type of pancreatic cancer and is more common than endocrine pancreatic cancer.[1]

Pancreatic adenocarcinoma may not cause early signs or symptoms and when present, the signs and symptoms are like the signs and symptoms of many other illnesses. Pancreatic adenocarcinoma is therefore difficult to detect and diagnose early, and is often not found until it has spread to other organs.[1]

When pancreatic adenocarcinoma cells are found in distant organs, such as the liver, lung and peritoneal cavity, the cancer is classified as stage IV (metastatic) adenocarcinoma of the pancreas.[1]

Stage IV adenocarcinoma of the pancreas is surgically unresectable and has a very low 5-year survival rate. Prior to the listing of nab-paclitaxel, the standard of care for stage IV pancreatic cancer was gemcitabine monotherapy. The submission proposed that nab-paclitaxel would be used in combination with gemcitabine for first-line treatment for stage IV pancreatic cancer.[2]

Pharmacology

Nanoparticle albumin-bound paclitaxel (nab-paclitaxel) 100 mg powder for injection (suspension) is an albumin nanoparticle form of paclitaxel with a mean particle size of approximately 130 nanometres. Paclitaxel exists in the nanoparticles in a non-crystalline, amorphous state. Each vial of nab-paclitaxel contains paclitaxel and human albumin in the ratio of 1:9. The paclitaxel is contained within nanoparticles that consist of a majority of paclitaxel bound to human albumin.[3]

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[1] National Cancer Institute, updated 23 December 2016, accessed 19 July2017. Available from: https://www.cancer.gov
[2] Abraxane® (nanoparticle albumin-bound paclitaxel), Public Summary Document, March 2014, http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2014-03/paclitaxel-nanoparticle-albumin-bound-psd-03-2014
[3] Abraxane® (nanoparticle albumin-bound paclitaxel), Australian Approved Product Information, East Kew VIC: Abraxis BioScience Australia Pty Ltd. Approved 17 October 2008, updated 3 September 2015. Available from https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2009-PI-01102-3&d=20170719161146224483

Therapeutic Goods Administration (TGA) approved indications

Nab-paclitaxel is approved for use in patients with:

- metastatic breast cancer after failure of anthracycline therapy,
- non-small cell lung cancer in combination with carboplatin, and
- metastatic adenocarcinoma of the pancreas in combination with gemcitabine.

Dosage and administration

To treat metastatic adenocarcinoma of the pancreas nab-paclitaxel should be administered in combination with gemcitabine.

The recommended dose of nab-paclitaxel is 125 mg/m^2 administered as an intravenous infusion over 30 minutes on Days 1, 8 and 15 of each 28-day cycle. The recommended dose of gemcitabine is 1000 mg/m^2 as an intravenous infusion over 30 minutes beginning immediately after the completion of nab-paclitaxel administration on Days 1, 8 and 15 of each 28-day cycle. [3]

The Product Information recommends dose reductions as shown in Table 1, and more specific dose modifications for neutropenia and/or thrombocytopenia and other adverse drug reactions (not shown).

Table 1: Dose level reductions for patients with metastatic adenocarcinoma of the pancreas

Dose Level	Nab-paclitaxel Dose (mg/m^2)	Gemcitabine Dose (mg/m^2)
Full dose	125	1000
1st level dose reduction	100	800
2nd level dose reduction	75	600
If additional dose reduction required	Discontinue treatment	Discontinue treatment

The current Product Information (PI) and Consumer Medicine Information (CMI) are available from the TGA (Product Information) and the TGA (Consumer Medicines Information).

PBS listing details (as at 1 July 2017)

Date of listing on PBS

Nab-paclitaxel was PBS listed on 1 November 2014 as an Authority Required (STREAMLINED) listing for Stage IV (metastatic) adenocarcinoma of the pancreas, under the item codes in Table 2.

Table 2: PBS listing of nab-paclitaxel

Item	Name, form & strength, pack size	Max. amount	Rpts	DPMA	Brand name and manufacturer
10150F Private	nanoparticle albumin-bound paclitaxel 100 mg injection, 1 vial	275 mg	11	$1282.72	Abraxane® Specialised Therapeutics Australia Pty Ltd
10165B Public	nanoparticle albumin-bound paclitaxel 100 mg injection, 1 vial	275 mg	11	$1228.06	

Source: the PBS website. If a Special Pricing Arrangement is in place this should be noted.

Restriction

Stage IV (metastatic) adenocarcinoma of the pancreas

The treatment must be in combination with gemcitabine, and the condition must not have been treated previously with PBS-subsidised therapy, and the patient must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Note: Not for use as neoadjuvant or adjuvant therapy.

Nab-paclitaxel is also PBS listed for metastatic or HER2 positive breast cancer. These listings have separate item codes as the maximum amount and repeats are different (580 mg and 5 respectively).

For details of the current PBS listing refer to the PBS website.

Relevant aspects of consideration by the Pharmaceutical Benefits Advisory Committee (PBAC)

The PBAC recommended nab-paclitaxel for PBS listing at its March 2014 meeting. The submission requested an Authority Required listing for first line treatment of locally advanced, unresectable or metastatic adenocarcinoma of the pancreas, in combination with gemcitabine.

The submission nominated gemcitabine monotherapy as the main comparator, arguing that gemcitabine monotherapy is the only therapy currently listed on the PBS for locally advanced unresectable or metastatic adenocarcinoma of the pancreas.

The PBAC considered that gemcitabine monotherapy was the appropriate comparator. The PBAC considered that FOLFIRINOX (folinic acid, fluorouracil, irinotecan and oxaliplatin) may potentially be a comparator, however noted at that time that this regimen was not PBS subsidised and treatment with this combination is associated with significant side effects.

The PBAC considered that the number of eligible patients was overestimated in the submission because Stage III patients were included, but overall considered the predicted estimates of use to be reasonable.

The PBAC noted that the overall cost was driven by the estimated market share. The PBAC noted that increasing the estimated market share increased the cost to the PBS.

The PBAC noted the TGA indication proposed by the Delegate, in which treatment is limited to patients with metastatic disease. The PBAC therefore recommended that the PBS restriction limit PBS-subsidised access to patients with metastatic (Stage IV) disease.

For further details refer to the Public Summary Document from the March 2014 PBAC meeting.

Approach taken to estimate utilisation

The submission used an epidemiological approach to estimate the number of pancreatic cancer patients eligible for nab-paclitaxel. The submission assumed that nab-paclitaxel in combination with gemcitabine would substitute for existing gemcitabine monotherapy.

AIHW Cancer incidence projections Australia, 2011 to 2020, of age-specific and age-standardised incidence rates of pancreatic cancer (per 100,000) were used to estimate the number of incident cases of pancreatic cancer. The submission stated the incidence of pancreatic cancer in patients aged less than 80 years and in those aged 80 and over were calculated separately as clinicians indicated that age is a significant factor in their choice of therapy.

The submission presented a range of sources to estimate the staging of pancreatic data. Most of the sources estimated the proportion of patients with Stage four disease to be approximately 50%. The Surveillance, Epidemiology and End Results [SEER] data from the United States (2003-2009) was selected as the primary source for the proportion of patients presenting with metastatic disease. It estimated 53% of patients present with Stage IV disease.

Several sources were also presented for the distribution of ECOG performance status, and the submission used a survey of Australian oncologists as the primary source. The proportion of patients with ECOG performance status of 0, 1 and 2 were 23.5%, 47.2% and 22.5% respectively.

The submission stated between 13 May and 23 October 2013, 163 patients were initiated on nab-paclitaxel for the treatment of metastatic pancreatic cancer, through an access program. The submission noted the expected prevalent population in the first year of listing will include grandfathered patients, and did not specifically estimate the number or separate them from initiating patients.

The submission requested PBS listing for two strengths of nab-paclitaxel, 100 mg and 250 mg vials. To estimate the number of prescriptions and vials, the financial estimates model considered the following drug regimens:

The number of prescriptions and vials was derived from cycles of treatment based on usage observed in the CA046 study.

The submission noted that in the trial the median treatment duration of patients in the nab-paclitaxel/gemcitabine arm was 119.0 days or 3.9 months. The median number of doses administered in the nab-paclitaxel/gemcitabine arm of the trial was 12 doses each of nab-paclitaxel and gemcitabine.

The submission was not considered by DUSC.

Methods

The analyses use date of supply data from the Department of Human Services (DHS) Medicare Supplied prescriptions database. Prescription data (including Repatriation PBS prescription, R/PBS) for nab-paclitaxel for adenocarcinoma of the pancreas were extracted from November 2014 to March 2017 using the item codes 10150F and 10165B.

Analyses were undertaken in SAS.

Length of treatment

To determine length of treatment, an initiating cohort was selected from the data. To exclude treatment experienced or grandfathered patients, any patients initiating nab-paclitaxel within the first three months of PBS listing were excluded. A six month cohort was selected to ensure sufficient time to follow up. The length of treatment for nab-paclitaxel was analysed for patients who initiated between 1 February 2015 and 31 July 2015.

Patients who initiated on 31 July 2015 were able to be followed for 609 days, to 31 March 2017. To ensure all patients were allowed equal follow up, only prescriptions supplied in the 609 days after initiation were considered.

The mean and median length of treatment for nab-paclitaxel were derived for the initiating cohort described above. Two calculations are presented. One calculation includes breaks in the calculation of treatment time, i.e., the time on treatment is the time between initiation and the last prescriptions. The second calculation assumes a patient's first episode of treatment ends after a treatment delay or break in therapy.

To determine the time indicative of a treatment delay or break, the nab-paclitaxel treatment regimen protocol and median time to resupply were considered. It was expected patients would be treated with nab-paclitaxel on days 1, 8 and 15 of each 28 day cycle. The median time to resupply was 7 days, however breaks of 14 days were also expected between treatment cycles. Patients were allowed three times 14 days (i.e. 42 days) to be supplied their next treatment. It was assumed that a patient had discontinued the episode of therapy if there was a break of more than 42 days.

Dose reduction and escalation

Dose reduction and escalation was examined for the cohort of patients who initiated in the six months between 1 February 2015 and 31 July 2015. The recommended dose of nab-paclitaxel is 125 mg/m^2. As the PBS does not contain patients' body surface area, the dose administered for each treatment was compared to that patient's initiating dose to calculate whether this treatment was higher, lower, or equal to the initial dose.

Vials and wastage

Through the Efficient Funding of Chemotherapy (EFC) prescribers must write dose-specific prescriptions, which specify the amount of active ingredient/s required for a single infusion or injection using milligrams or other relevant units of measure. Dispensing software includes an algorithm which calculates the most cost-efficient combination of vial sizes that make up the required patient dose (one prescription) and calculates the level of remuneration paid.

For this analysis the number of supplied vials for each prescription was calculated from the dose (mg) supplied using the relationships in Table 3.

Table 3: Calculation of vials with 100 mg vial listed

Quantity	Vials (100 mg)
Less than 100	1
Between 101 and 200	2
Between 201 and 300	3
Between 301 and 400	4
Between 401 and 500	5

The number of vials that would have been supplied, if a 250 mg strength vial was listed, was calculated for the actual quantities using the relationships in Table 4.

Table 4: Calculation of vials with 100 mg and 250 mg vials listed

	100 mg vials	250 mg vials
Less than 100	1	0
Between 101 and 200	2	0
Between 201 and 250	0	1
Between 251 and 350	1	1
Between 351 and 450	2	1
Between 451 and 500	0	2

For both scenarios wastage was calculated as the difference between the total volume supplied and the quantity used.

Limitations of the data

Nab-paclitaxel is PBS listed for pancreatic cancer and breast cancer under separate PBS item codes as the maximum amount and repeats are different for the two listings. The maximum amount for pancreatic cancer is 275 mg, and the maximum amount for breast

cancer is 580 mg. Data were extracted for the pancreatic cancer PBS item codes only, however it is possible that a small number of the higher doses were used to treat breast cancer. Of 37,225 supplies recorded, 199 were of quantities higher than 275 mg, which is equivalent to 0.535%.

Results

Analysis of drug utilisation

Overall utilisation

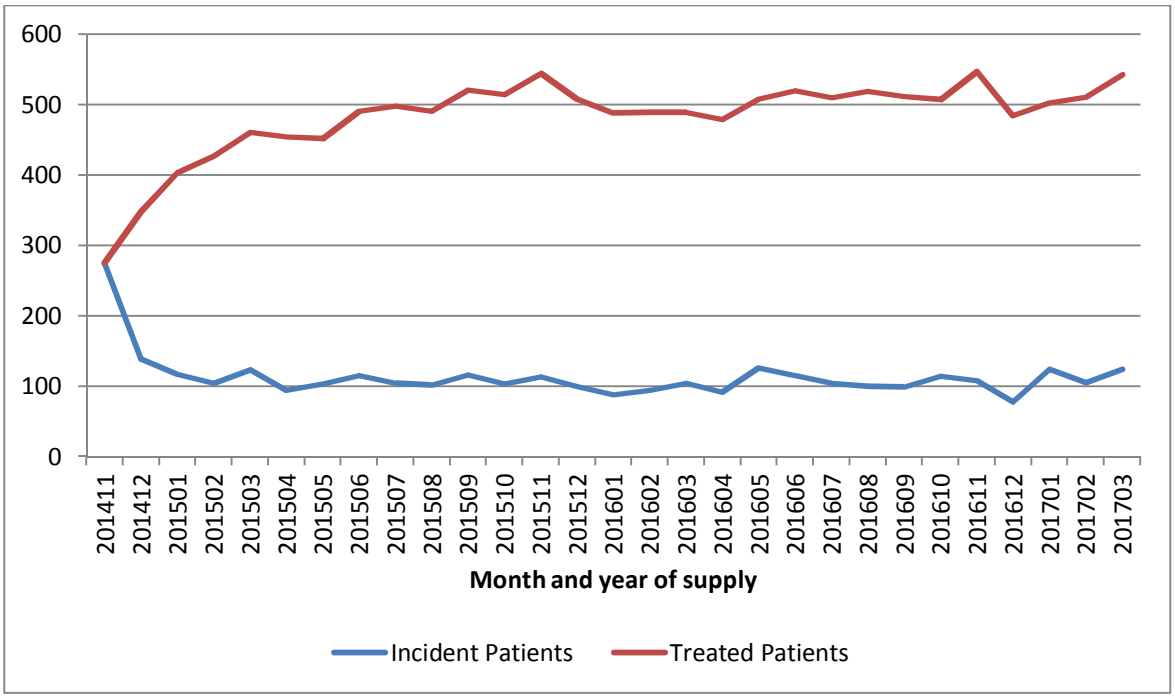

Figure 1: Initiating and prevalent treated patients of nab-paclitaxel for adenocarcinoma of the pancreas

Figure 1 shows nab-paclitaxel had a high initial uptake in the first two months, and the number of patients initiating treatment stabilised by the third month of listing. This pattern aligns with the expectations presented in the submission, which stated uptake would be rapid and use was not expected to grow significantly in subsequent years.

The number of initiating patients in the first two months of PBS listing were 275 and 139 respectively (414 in first two months). The submission stated 163 patients were initiated on the access program between 13 May and 23 October 2013, but did not state the total number of patients receiving nab-paclitaxel through the access program. It is reasonable that between 275 and 414 patients were receiving nab-paclitaxel through the access program by November 2014.

The number of prevalent treated patients stabilised approximately nine months after the PBS listing of nab-paclitaxel for adenocarcinoma of the pancreas, which suggests patients are not remaining on treatment long term.

Length of treatment

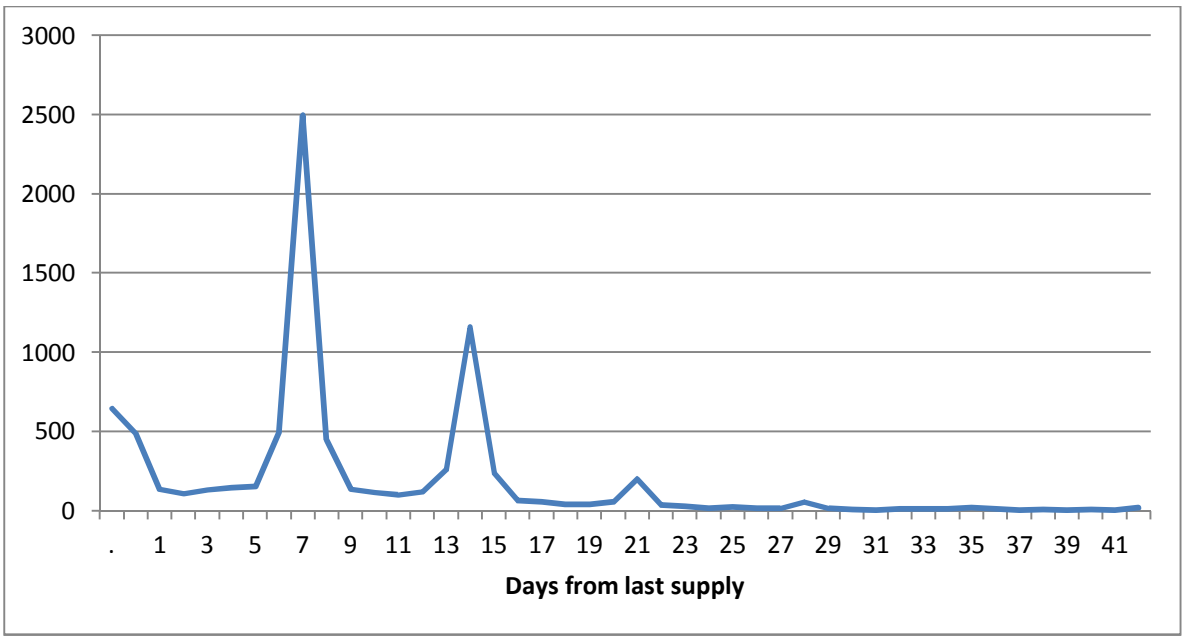

Figure 2: Time to resupply for the initiating cohort (including prescriptions after breaks)

Figure 2 above shows the time to resupply matches those expected due to the administration recommendations. There were 152 prescriptions (less than 2%) that were supplied more than 42 days after the previous treatment. These prescriptions have been removed from this graph. The largest peak of resupply was at seven days after initiation. There is a smaller peak at 14 days, likely due to the space between treatment on day 15 and the next cycle starting after 29 days. Initiations (643) have not been removed from this graph.

Table 5: Length of treatment (including breaks)

	Number of Patients	Length of Treatment (days)	
		Mean	Median
Younger than 80	608	141.31	104
80 or older	35	99.69	80
Total	643	139.05	101

Table 6: Length of treatment (treatment break indicates discontinuation)

	Number of Patients	Length of Treatment (days)	
		Mean	Median
Younger than 80	608	98.61	82.5
80 or older	35	67.23	64
Total	643	96.90	80

The median length of treatment in the trial was 119 days. The median length of treatment including breaks was 101 days, which is equivalent to 3.61 treatment cycles. Of the 643 patients included in the initiating cohort, only nine were continuing treatment at the end of the 609 day follow up. The second calculation of length of treatment defines patients as stopping treatment if there is a break of 42 days between treatments. Of the 643 patients in the cohort, 126 (approximately 20%) had a treatment delay or break of more than 42 days and were assumed to have discontinued. The median length of treatment in this analysis was 80 days, which is equivalent to 2.86 28 day cycles.

The length of treatment shown in Tables 5 and 6 confirms that patients are not remaining on treatment long term, as expected from Figure 2. Half of initiators stop treatment 12 weeks after initiation and not unexpectedly older patients are treated for shorter durations than younger patients.

Dose reduction and escalation

Figure 3 below graphs the percentage dose reduction or escalation from the initial dose, for all treatments administered to this patient cohort. Initiating doses (643) and doses equal to the initiating dose (4,729) are not shown in this figure.

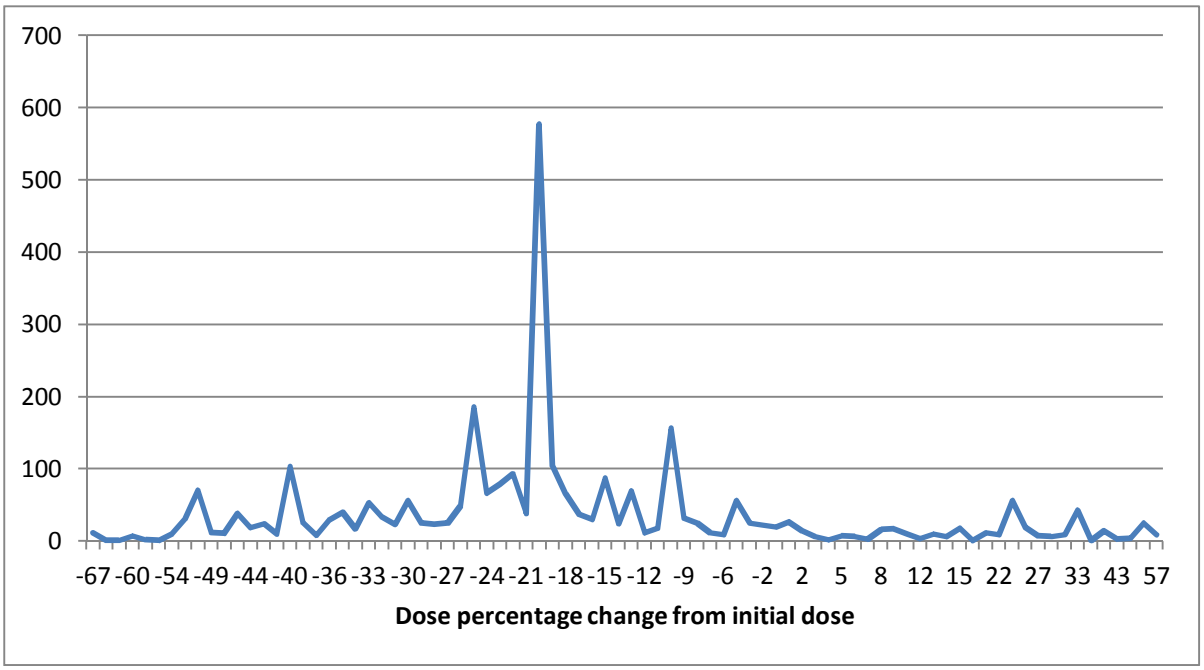

Figure 3: Dose reduction or escalation from initial dose

For uncensored treatments, the proportions in Table 7 below summarises dose reduction and escalation for the six month cohort of patients who initiated between 1 February 2015 and 31 July 2015. The table summarises the number of initiating doses, which is equal to the number of initiating patients, and the number of doses that were administered to these patients, grouped by whether these doses were higher, lower, or equal to the patients' initiating dose.

Table 7: Dose reduction and escalation for all treatments received by the initiating cohort

	Number	Percent
Initiating doses	643	8%
No change from initial dose	4,729	57%
Reduction from initial dose	2,603	31%
Escalation from initial dose	365	4%
Total doses	8,340	

More than thirty percent of treatments administered to patients in the initiating cohort were dose reductions.

Utilisation by relevant sub-populations/regions or patient level analysis

Table 8 below shows older patients (over the age of 80) tend to have lower doses, but the small numbers of these patients do not affect the overall mean or median.

Table 8: Mean and median dose for patients older and younger than 80

Year	Age Range	Number patients	Number doses	Mean dose (mg)	Median dose (mg)
2015	Younger than 80	1,503	14,696	194	200
	80 or older	99	740	161	160
	Total	199	15,436	192	200
2016	Younger than 80	1,602	15,146	191	195
	80 or older	112	828	163	165
	Total	1,708	15,974	189	193
Total[a]	Younger than 80	3,074	35,388	192	200
	80 or older	223	1,837	163	170
	Total	3,284	37,225	191	200

Note: As age is determined by the date of supply of the medicine, patients may be counted more than once in each year and therefore numbers of patients older and younger than 80 will be larger than the total number. Patients treated in both 2015 and 2016 are counted in each year and cannot be summed.
a: Total includes patients treated in November and December 2014 and January to March 2017.

Analysis of actual versus predicted utilisation

Between PBAC recommendation and PBS listing, the submission's estimates were updated to reflect the recommendation of the PBAC. Patients with locally advanced unresectable cancer and patients with ECOG status of 3 were excluded from the estimates, and the estimate of vials was changed to account for the 250 mg vial not being listed.

Nab-paclitaxel was listed with a special pricing arrangement, with the effective price [redacted] lower than the published DPMQ. Expenditure caps are in place, which have not been reached. A 5% statutory price reduction was applied to nab-paclitaxel on 1 April 2016. The special pricing arrangement was not changed, so the effective price was also reduced by 5%.

Table 9: Analysis of actual versus predicted utilisation of nab-paclitaxel for adenocarcinoma of the pancreas

		2014	2015	2016	2017
Patients	Predicted	1,508	1,499	1,550	1,594
	Actual	414	1,599	1,708	771
	% Difference (A-P)/P		+7%	+10%	
Prescriptions	Predicted	20,151	20,208	20,895	21,484
	Actual	1,656	15,436	15,974	4,159
	% Difference (A-P)/P		-24%	-24%	
Vials (100 mg)	Predicted	54,101	54,576	56,432	58,022
	Actual	3,909	35,618	36,929	9,601
	% Difference (A-P)/P		-35%	-35%	

Patient numbers in 2015 and 2016 were similar to estimated numbers. The number of treatments these patients were supplied were much lower than predicted, and the number of vials supplied were lower again.

Vials and wastage

When recommending the 100 mg vial of nab-paclitaxel, the PBAC noted that only the 100 mg vial of nab-paclitaxel has been approved by the TGA, and considered that the absence of the 250 mg vial may increase wastage.

Table 10: Vials and wastage of nab-paclitaxel with and without a 250 mg vial listed

	Year	2014	2015	2016	2017
With 100 mg vial	Vials	3,909	35,618	36,929	9,601
	Wastage (mg)	65,422	596,274	667,018	167,118
With 100 mg and 250 mg vials	100 mg vials	2,026	20,630	21,130	5,535
	250 mg vials	650	5212	5519	1,403
	Wastage (mg)	39,622	400,474	466,868	111,268
Wastage difference (mg)		25,800	195,800	200,150	55,850

This analysis confirms that drug wastage would be less if the 250 mg vial had been listed.

Discussion

Pancreatic adenocarcinoma is often not diagnosed until it has spread to other organs and is classified as stage IV (metastatic) adenocarcinoma of the pancreas. The number of treated patients was similar to expected. The use of Australian cancer incidence projections from the AIHW therefore appears to have been a reasonable and accurate source of likely patient numbers. The number of prevalent treated patients does not appear to be growing, which is to be expected in metastatic disease with poor prognosis.

The high and rapid uptake of PBS listed nab-paclitaxel within the pancreatic cancer market is reasonable given the lack of other available treatments for pancreatic cancer, and the estimated number of patients receiving treatment through the access program at the time of listing.

The data indicates a substantial proportion of use is at reduced dose. One third of subsequent doses were lower than the initiating dose. The submission noted that the trial allowed patients to dose reduce, however the format of the submission estimates make it difficult to compare the number of patients who required dose reductions or the amount of the dose reductions.

The graph of time to resupply suggests patients are mostly following the recommended dosing schedule of receiving treatments on days 1, 8, and 15 of each 28 day cycle. Where treatments are administered later than 7 or 14 days, the highest occurrence is treatments 21 and 28 days after the last supply. This is likely due to patients being treated on the same day of the week, but with a delay of one or two weeks. This pattern could also be due to differences between the date the prescription was dispensed by the pharmacy and the date the medicine was administered to the patient.

The median number of doses administered in the nab-paclitaxel/gemcitabine arm of the trial was 12 doses, which is equivalent to four full treatment cycles. The median length of treatment in the trial was 119 days, which is equivalent to 4.25 28 day treatment cycles.

In the PBS data, when breaks were included, the treatment duration was similar to the duration predicted by the trial. When discontinuation was assumed to have occurred after a break of more than 42 days, 20% of patients were assumed to have stopped treatment earlier, and the median length of treatment decreased by three weeks.

The proportion of patients with dose delays longer than 42 days (20%) and the proportion of treatments which are dose reductions (30%) may explain the lower than predicted number of prescriptions (24%) and lower than predicted number of vials (35%) in 2015 and 2016. It is likely dose reductions are due to drug related adverse events, such as neutropenia and thrombocytopenia, as outlined in the PI. Dose delays or treatment breaks may be due to drug related adverse events, other disease related events, or other reasons. It is not possible to determine the reason from PBS data.

Given the course of the disease, it is likely future use for pancreatic cancer will remain at or close to the current level. Use may be displaced if new therapies are PBS listed. This possibility is likely several years away, as investigation into several to be named drugs do not appear to have reached phase III of clinical trials.[4]

[4] National Library of Medicine (NLM), https://clinicaltrials.gov/ct2/results?cond=adenocarcinoma+of+the+pancreas&term=&cntry1=&state1=&Search=Search

DUSC consideration

DUSC noted the number of prevalent patients had stabilised after 6 months of listing. DUSC commented it was expected that for most patients there would not be long term or ongoing treatment due to the poor prognosis of pancreatic cancer.

DUSC noted the report found that the number of patients was very similar to predicted, but the number of vials and prescriptions were lower than predicted. DUSC noted the analysis of dose reductions presented in the report and agreed dose reductions are likely related to side effects or disease related issues. DUSC considered that dose reductions may explain some of the differences between predicted and actual use. DUSC noted the length of treatment analysis showed peaks of prescription refill at 21 and 29 days and considered that this is likely due to toxicity and treatment breaks before further supply. DUSC commented that PBS patients are likely to be older and sicker than the clinical trial patients, and considered these results make sense in the context of treating pancreatic cancer in practice.

DUSC considered that the risk of use outside of the PBS restriction, for example in patients with an ECOG performance status greater than 2, was very small, as patients would need to be reasonably fit to be treated with dual therapy.

DUSC noted that not all components of standard first line aggressive treatment for pancreatic cancer, FOLIFIRINOX (folinic acid, fluorouracil, irinotecan and oxaliplatin), were subsidised through the PBS for pancreatic cancer at the time that nab-paclitaxel was being considered for listing on the PBS. Since this time these listings have become unrestricted and may be prescribed through the PBS for pancreatic cancer. DUSC considered use may be affected by the changing of chemotherapy restrictions to unrestricted listings. However, DUSC noted patients treated with FOLIFIRINOX (folinic acid, fluorouracil, irinotecan and oxaliplatin) would not be able to access PBS nab-paclitaxel in second line. DUSC noted there are no other new drugs that are close to Phase III trials.

DUSC noted the wastage analysis presented in the report, which calculated a 250 mg vial would result in approximately a third less wastage. DUSC considered this was an issue as the large vial size was expected at the time of listing.

DUSC actions

- DUSC requested that the report be provided to the PBAC.
- DUSC requested the PBAC should consider whether to refer the matter of the lack of a 250 mg vial leading to wastage to the Department to address with the sponsor.

Context for analysis

The DUSC is a Sub Committee of the Pharmaceutical Benefits Advisory Committee (PBAC). The DUSC assesses estimates on projected usage and financial cost of medicines.

The DUSC also analyses data on actual use of medicines, including the utilisation of PBS listed medicines, and provides advice to the PBAC on these matters. This may include outlining how the current utilisation of PBS medicines compares with the use as recommended by the PBAC.

The DUSC operates in accordance with the quality use of medicines objective of the National Medicines Policy and considers that the DUSC utilisation analyses will assist consumers and health professionals to better understand the costs, benefits and risks of medicines.

The utilisation analysis report was provided to the pharmaceutical sponsors of each drug and comments on the report were provided to DUSC prior to its consideration of the analysis.

Sponsors' comments

Specialised Therapeutics Australia Pty Ltd: The sponsor has no comment.

Disclaimer

The information provided in this report does not constitute medical advice and is not intended to take the place of professional medical advice or care. It is not intended to define what constitutes reasonable, appropriate or best care for any individual for any given health issue. The information should not be used as a substitute for the judgement and skill of a medical practitioner.

The Department of Health (DoH) has made all reasonable efforts to ensure that information provided in this report is accurate. The information provided in this report was up-to-date when it was considered by the Drug Utilisation Sub-committee of the Pharmaceutical Benefits Advisory Committee. The context for that information may have changed since publication.

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