

7.13 NETUPITANT and PALONOSETRON netupitant 300 mg + palonosetron 0.5 mg, capsule Akynzeo®, Specialised Therapeutics Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor resubmission requested an Authority Required (STREAMLINED) listing on the General Schedule and Section 100 (Efficient Funding of Chemotherapy - Related Benefits), for the prevention of nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy (HEC), and anthracycline plus cyclophosphamide (AC) based regimens in patients with breast cancer.

2 Requested listing

- 2.1 The submission requested the following new listings. The proposed ex-manufacturer price (\$ [REDACTED]) is unchanged from the previous submissions:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
GENERAL SCHEDULE					
NETUPITANT WITH PALONOSETRON Capsule 300 mg + 0.5 mg, 1	1	5	\$ [REDACTED]	Akynzeo®	STA
SECTION 100 (CHEMOTHERAPY)					
NETUPITANT WITH PALONOSETRON Capsule 300 mg + 0.5 mg, 1	1	5	\$ [REDACTED]		

Category / Program	GENERAL – General Schedule (Code GE)* Section 100 – Chemotherapy related benefits
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners* <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Nausea and vomiting
PBS Indication:	Nausea and vomiting
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 condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with dexamethasone; AND Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

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Prescriber Instructions	No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.
Administrative Advice	No increase in the maximum quantity or number of units may be authorised. No Increase in the maximum number of repeats may be authorised. This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

Category / Program	GENERAL – General Schedule (Code GE)* Section 100 – Chemotherapy related benefits
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners* <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Nausea and vomiting
PBS Indication:	Nausea and vomiting
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 condition must be associated with cytotoxic chemotherapy being used to treat breast cancer; AND The treatment must be in combination with dexamethasone; AND Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline;
Prescriber Instructions	No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.
Administrative Advice	No increase in the maximum quantity or number of units may be authorised. No Increase in the maximum number of repeats may be authorised. This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

3 Background

- 3.1 TGA status at the time of PBAC consideration: Netupitant + palonosetron (NEPA) was registered with the Therapeutic Goods Administration (TGA) in May 2015. NEPA is indicated in adult patients for:
- prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy; and
 - prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.
- 3.2 NEPA has previously been considered by the PBAC at the March 2015 meeting and July 2015 meeting. The major submission in March 2015 was rejected by the PBAC as there was no recognised unmet clinical need for this population of patients and the clinical place for NEPA was not established in the major submission (paragraph 7.1 of the March 2015 minutes). Further, the PBAC was concerned that the fixed dose combination guidelines were not addressed in the submission. The minor submission in July 2015 was rejected by the PBAC as there was still uncertain clinical need for this population of patients, the fixed dose combination guidelines were not addressed

in the resubmission, and there was potential for leakage.

- 3.3 The current resubmission sought to address the FDC guidelines, describe the clinical need for NEPA, and propose a risk sharing arrangement to address potential leakage.

Table 1: Summary of key issues from the previous submission and current resubmission

	NEPA July 2015	Current re-submission
Requested price	Effective DPMQ Section 85: \$ [REDACTED] Section 100: \$ [REDACTED]	No change in ex-manufacturer price, DPMQs updated Section 85: \$ [REDACTED] Section 100: \$ [REDACTED]
Uncertain clinical need	Inclusion of NEPA in National Comprehensive Cancer Network (NCCN) guidelines Improved adherence to treatment guidelines Improved patient compliance Impact on resource use PBAC Comment: The PBAC noted the updated NCCN guidelines but considered the clinical need for the FDC in Australia was not established by the resubmission. (7.2, July 2015 PBAC minutes)	No change in claim, provided additional references: Burke TA, Wisniewski T, Ernst FR. Resource utilization and costs associated with chemotherapy-induced nausea and vomiting (CINV) following highly or moderately emetogenic chemotherapy administered in the US outpatient hospital setting. Support Care Cancer. 2011;19(1):131-140. eviQ Cancer Treatments Online; www.eviq.org.au. 2015. Lai J, Homung I, Greenberg S. Predictors of chemotherapy-induced nausea and vomiting (CINV) presentations to a symptom urgent review clinic (SURC) at Western Health, Melbourne. Lai J, Homung I, Greenberg S. Asia-Pac J Oncology 2014; 10(Suppl.6): 52-68. Mayer DK, Travers D, Wyss A, Leak A, Waller A. Why do patients with cancer visit emergency departments? Results of a 2008 population study in North Carolina. J Clin Oncol 2011;29:2683-2688. McKenzie H, Hayes L, White K, Cox K, Fethney J, Boughton M, Dunn J. Chemotherapy outpatients' unplanned presentations to hospital: a retrospective study. Support Care Cancer (2011) 19:963–969. Schenberg T, Greenberg S. A retrospective audit of requirement for medical review in the Chemotherapy Day Unit (CDU) at Western Health (WH), presented at MOGA 2013.
Economic evaluation	Cost-minimisation, with the equi-effective doses calculated during the submission. PBAC Comment: The PBAC noted that the economic evaluation remained the same as that	No change in economic evaluation.

	NEPA July 2015	Current re-submission
	from March 2015, which was a cost comparison rather than a cost-minimisation. (7.8, July 2015 PBAC minutes)	
FDC guidelines	PBAC Comment: The PBAC remained concerned that the Fixed Dose Combination guidelines were not addressed in the submission. (7.3, July 2015 PBAC minutes)	Provided table addressing FDC guidelines (see Table 4)
Potential for leakage	PBAC Comment: The PBAC considered however, that despite the restriction, leakage was likely to occur in the population of patient scheduled to receive moderately emetogenic chemotherapy and also to patient who would usually only receive the 5-HT ₃ RA component because of the dose form being one tablet. (7.5, July 2015 PBAC minutes)	Proposed a risk sharing arrangement to address risk of use beyond the proposed restriction (see paragraph 6.7)

Source: Compiled for the Minor Overview

DPMQ = dispensed price for maximum quantity; FDC = fixed dose combination; NEPA = netupitant/palonosetron; PBAC = Pharmaceutical Benefits Advisory Committee; 5-HT₃ RA = serotonin receptor antagonist

4 Clinical place for the proposed therapy

- 4.1 The resubmission suggested, as previously, that the availability of a FDC regimen on the PBS will improve adherence to treatment guidelines at time of HEC administration, improve patient compliance in the home, and impact on resource use. The resubmission proposed that the key benefits to patients and nursing staff by developing NEPA as a FDC of two mandatorily combined single agents are the reduction in pill burden, greater convenience and potentially improved compliance. Following the FDA approval of NEPA, the NCCN guidelines for HEC emesis prevention were updated to specifically include NEPA (see Figure 1 of the resubmission).

5 Comparator

- 5.1 The previous submissions considered by the PBAC in March 2015 and July 2015 nominated aprepitant plus a 5-HT₃ receptor antagonist (5-HT₃ RA). This was unchanged. The PBAC has previously considered this as the appropriate comparator.

For more detail on PBAC's view, see section 7 "PBAC outcome"

6 PBAC consideration of the evidence

Sponsor hearing

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

Consumer comments

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

Clinical trials

6.3 As a minor submission, no new clinical data were presented in the re-submission.

Comparative effectiveness and harms

6.4 The PBAC previously considered that despite the wide confidence intervals, the clinical claim that NEPA was non-inferior to aprepitant plus a 5-HT₃ RA was reasonably well supported for patients scheduled to receive highly emetogenic chemotherapy and in patients with breast cancer scheduled to receive anthracycline plus cyclophosphamide based regimens (paragraph 7.6 of the March 2015 minutes).

6.5 The PBAC previously considered that the claim of non-inferior comparative safety was reasonable (paragraph 6.18 of the March 2015 minutes).

Economic analysis

6.6 In the previous major submission considered by PBAC in March 2015, the submission presented a cost-minimisation analysis against aprepitant plus a 5-HT₃ RA. The PBAC considered the economic evaluation presented to be a cost comparison, rather than a cost-minimisation analysis (paragraph 7.7 of the March 2015 minutes), noting that the cost of the FDC is less than the cost of aprepitant alone.

Estimated PBS usage & financial implications

6.7 Table 2: Estimated financial implications for the PBS

	Year 1 (2016)	Year 2 (2017)	Year 3 (2018)	Year 4 (2019)	Year 5 (2020)
Estimated PBS Services for Akynzeo	██████	██████	██████	██████	██████
Total cost	\$██████	\$██████	\$██████	\$██████	\$██████
Average patient co-payment	\$██████	\$██████	\$██████	\$██████	\$██████
Net cost to Government for the drug	\$██████	\$██████	\$██████	\$██████	\$██████
Net cost for aprepitant/5-HT ₃ RA	\$██████	\$██████	\$██████	\$██████	\$██████
Overall Net Cost to PBS	-\$██████	-\$██████	-\$██████	-\$██████	-\$██████

Source: Submission, Table 4 p.10

6.8 The minor submission estimated that there will be ██████ 10,000 – 50,000 prescriptions for NEPA in Year 5 of listing. This is unchanged from the previous July 2015 resubmission. The current resubmission estimated a net save to the PBS of \$██████ in Year 5 of listing, with a total net save to the PBS of less than \$10 million over the first 5 years of listing.

- 6.9 The sponsor proposed a risk sharing arrangement where any usage beyond the proposed estimates for NK1 RA use in HEC and AC breast cancer would be subject to a rebate of 30% of the cost of Akynzeo. This would occur for any usage greater than 100% of the total HEC/AC breast cancer market.

Table 3: Estimated PBS services per year

	Year 1 (2016)	Year 2 (2017)	Year 3 (2018)	Year 4 (2019)	Year 5 (2020)
Total PBS Services for NK1 RAs	████	████	████	████	████
NK1 RAs use in HEC/AC-MEC	████	████	████	████	████
Estimated PBS Services for Akynzeo	████	████	████	████	████

Source: Submission, Table 5 p.11

The estimated use of NK1 RAs is based on the streamlined Authority Required use of aprepitant in HEC and AC breast cancer, adjusted by a growth factor of 4% annually.

- 6.10 The PBAC advised that a risk sharing arrangement should include a subsidisation cap where higher than expected use of NEPA defaults to the equivalent cost of a 5-HT₃ receptor antagonist. The PBAC considered that caps should be based on estimates of NEPA use in HEC and AC breast cancer indications, as presented in the submission. The PBAC reiterated that there is substantial risk of leakage into the population of patients scheduled to receive moderately emetogenic chemotherapy and also to patients who would usually only receive the 5-HT₃ RA component because of the dose form being one tablet.

Quality Use of Medicines

- 6.11 The re-submission made a claim of improved compliance with NEPA for delayed chemotherapy-induced nausea and vomiting (as in the previous July 2015 resubmission). This was based on a study by Chan et al (2012) that examined the association between non-compliance and delayed phase patients with breast cancer who received anthracycline plus cyclophosphamide based regimens (Source: p.6 of the resubmission). The submission claimed that the likely improvement of patient compliance was due to a simplification and convenience of therapy.
- 6.12 The following table was provided in the submission to address the fixed dose combination guidelines:

Table 4: Matters to consider for the listing of fixed combination products
(abridged table from the resubmission)

PBAC Guidelines	Application to NEPA
Information requests	
Provide information as part of the response to Part II, Subsection A.2 to show that the combination product has been approved by the TGA, or is recommended for approval by the TGA, and meets all clinical criteria required by the TGA. Confirm that any requested restriction is consistent with any restriction for each component of the combination product.	NEPA was registered with the Therapeutic Goods Administration (TGA) in May 2015. NEPA is indicated in adult patients for: <ul style="list-style-type: none"> prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy; and prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.
For each component of the combination product, provide information as part of the response to Part II, Subsection A.3 to show that: <ul style="list-style-type: none"> it is (preferably) listed on the PBS or funded on the NIP the doses are consistent with the doses of the combination product. 	Neither of the component products are registered with the TGA, nor listed on the PBS. <ul style="list-style-type: none"> Although palonosetron is listed on the PBS, oral palonosetron is not listed on the PBS. Netupitant is not listed on PBS, or registered for use as a single agent.
Also as part of the response to Part II, Subsection A.3, show that listing the combination product would not result in: <ul style="list-style-type: none"> inappropriate dosing of either component (eg the combination product should not contain components for which individual dose titration is preferable) unnecessary proliferation of products or dose forms. 	There is no issue regarding inappropriate dosing or unnecessary proliferation of dose forms as palonosetron is only listed for one strength and netupitant is not listed. Listing the fixed dose combination of an NK1 inhibitor and 5-HT ₃ receptor antagonist is suggested by the resubmission to likely improve adherence to treatment guidelines.
As part of the response to Part II, Subsection A.4, identify the main comparator products and explain the reasons for the selection of these comparators.	The main comparator is aprepitant plus a 5-HT ₃ receptor antagonist.
Provide data as part of submission section B to show additive (not necessarily synergistic) beneficial effectiveness of the components.	Data from NETU-08-18 presented in the original major submission demonstrate the additive effectiveness of the FDC over palonosetron monotherapy. Further, netupitant has synergistic activity with palonosetron, in contrast to only additive activity shown by the other 5-HT ₃ RA/NK1 receptor antagonist combinations (Stathis et al., 2012).
Substantiate any claims of improved patient convenience or compliance in terms of their impact on improving health outcomes (as part of the response to submission sections B or C), reducing provision of other health care resources (as part of submission sections B, C or D), or reducing expenditure in the Australian Government health budget (as part of submission section E).	The availability of a fixed dose combination is likely to improve adherence to guidelines, as co-prescription data suggests that approximately one quarter of aprepitant use is prescribed as monotherapy. The listing of NEPA will result in some cost savings to patients (general) and the PBS (concession card holders) for cost of 5-HT ₃ receptor antagonist.
Provide an analysis as part of submission section E to show that listing the combination product would not encourage or result in an inappropriate increase in overall use of its individual components, nor in inappropriate use of one or more of those components in specific patient groups.	The listing of NEPA is unlikely to increase the use of palonosetron. NEPA will substitute for aprepitant in combination with a 5-HT ₃ receptor antagonist (so will actually decrease the number of palonosetron prescriptions).

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PBAC Guidelines	Application to NEPA
Identifying the main comparators	
<p>More than one comparison should usually be presented for a combination product, such as one or more of the following:</p> <ul style="list-style-type: none"> • the combination product against its component products given concomitantly as the basis for a cost-minimisation recommendation (this need not apply where the combination product consists of the individual dosage forms in a composite packaging) • the combination product (or its components given concomitantly) against each of the component products given alone as the basis for establishing at least an additive beneficial effectiveness (or the basis to establish no loss of beneficial effectiveness of the components in the case of fixed combination vaccine products; see Part IV, Product type 3), thus involving at least two comparisons depending on the number of components in the fixed combination product • the combination product against the therapy that prescribers would most replace in practice, should this be expected to vary from the current concomitant use of the individual components. 	<ul style="list-style-type: none"> • There are no studies comparing the FDC with the individual components used concomitantly. In the key clinical trials, the fixed dose combination was used in NETU-10-29, while netupitant and palonosetron were administered concomitantly in NETU-07-07 • Data from NETU-08-18 can be used to demonstrate the additive effectiveness of the FDC over palonosetron monotherapy. However no data are available to demonstrate additive effectiveness of NEPA over netupitant which has not been developed as a monotherapy agent. • There are two RCTs comparing NEPA with the main comparator, aprepitant plus a 5-HT₃ receptor antagonist. The 5-HT₃ receptor antagonist included in study NETU-10-29 was palonosetron while, in study NETU-07-07, 32mg iv ondansetron was co-prescribed.
Pricing of fixed dose combination products	
<p>If the request for listing is on a cost-minimisation basis against the component products, the pricing of a combination product would normally be no greater than the sum of its individual components (at the current price to pharmacist level for PBS products or at the Commonwealth price for NIP products), usually calculated on a per milligram basis.</p> <p>Where the combination product(s) are expected to substitute for two or more strengths of the component products, the price to pharmacist should reflect the sum of the individual components as a function of the expected proportions of substitution.</p> <p>Support any request for a price advantage with evidence of acceptable cost-effectiveness via improved health outcomes or acceptable cost offsets.</p>	<p>The pricing of NEPA was set on the basis of equivalence with aprepitant, with no cost assigned to the 5-HT₃ RA component. The sponsor was also able to offer a lower price, so that the cost of the FDC is less than the cost of aprepitant alone.</p> <p>n/a</p> <p>n/a</p>
Providing advice under subsection 101(4AC)	
<p>Identify whether the fixed combination product meets the definition of a combination item.</p>	<p>The product is a fixed dose combination, however, as neither netupitant, nor oral palonosetron are listed on the PBS, NEPA <i>is requested</i> to be listed on the F1 formulary instead of the combination schedule.</p>
<p>Identify and define the alternative therapies.</p>	<p>The comparator is aprepitant in combination with a 5-HT₃ receptor antagonist</p>

PBAC Guidelines	Application to NEPA
Provide information to enable PBAC to decide whether it is satisfied that the combination item provides, for some patients: <ul style="list-style-type: none"> • a significant improvement in compliance or • a significant improvement in efficacy or • a significant reduction in toxicity over the alternative therapies. 	NEPA appears to be as effective and safe as the use of aprepitant in combination with a 5-HT ₃ receptor antagonist. Co-prescription data indicates that up to one quarter of aprepitant scripts are issued as monotherapy (HI Connections data). The availability of NEPA as a fixed dose combination will improve adherence to Consensus guidelines for patients scheduled to receive HEC and AC chemotherapy regimens.

Source: Submission, Table 3 p.8 (abridged)

For more detail on PBAC's view, see section 7 "PBAC outcome"

7 PBAC Outcome

- 7.1 The PBAC recommended listing netupitant + palonosetron fixed dose combination (NEPA FDC) as an Authority Required STREAMLINED benefit on the General Schedule and under the Section 100 program Efficient Funding of Chemotherapy – Related Benefits, for the prevention of nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy and anthracycline plus cyclophosphamide based regimens in patients with breast cancer.
- 7.2 Listing was recommended at the price proposed in the submission, with the PBAC noting the lower DPMQ offered for NEPA compared with aprepitant. The PBAC noted that the economic analysis presented in the original submission was a cost comparison and the equi-effective doses were difficult to establish, however considered an assumption that each chemotherapy course would be treated with one capsule of NEPA FDC or one capsule of aprepitant 165 mg plus a 5-HT₃ RA to be reasonable.
- 7.3 The PBAC considered that the clinical need for the NEPA FDC remained low, and noting the very high potential for leakage, considered that a robust risk sharing arrangement would be required to address this uncertainty.
- 7.4 As previously, the PBAC accepted aprepitant with a 5-HT₃ RA as the appropriate comparator, and considered the clinical claim that NEPA is non-inferior to aprepitant with a 5-HT₃ RA reasonable.
- 7.5 The PBAC noted that the submission claimed that there would be a net saving to the PBS as a result of listing NEPA. The PBAC considered that this saving would only eventuate where NEPA substitutes for aprepitant plus a 5-HT₃ RA. If NEPA substitutes for 5-HT₃ RA alone, or is used outside of the proposed restriction, the total cost of PBS medicines for the prevention of nausea and vomiting will increase.
- 7.6 The PBAC advised that the NEPA FDC should not be treated as interchangeable with any other individual drugs on an individual patient basis, however that therapeutically, NEPA FDC could be considered interchangeable with the free combination of aprepitant with a 5-HT₃ RA.
- 7.7 The PBAC noted that the submission proposed that the availability of NEPA as a

fixed dose combination would improve adherence. The PBAC decided it was not satisfied as required by subsection 101(4AC) of the *National Health Act 1953* (Act) and therefore will not provide advice to the Minister under that section.

- 7.8 The PBAC noted that the submission's request for NEPA FDC to be listed on the F1 formulary was not a matter for the Committee, however noted Departmental advice that NEPA FDC did not meet the Act's requirements for inclusion on the F1 formulary.
- 7.9 The PBAC advised that NEPA is suitable for prescribing by nurse practitioners under the general schedule listing.
- 7.10 The PBAC recommended that the Safety Net 20 Day Rule should not apply.
- 7.11 The PBAC noted that this submission is not eligible for an Independent Review.

Outcome:

Recommended

8 Recommended listing

8.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
GENERAL SCHEDULE				
NETUPITANT WITH PALONOSETRON Capsule 300 mg + 0.5 mg, 1	1	5	Akynzeo®	STA
SECTION 100 (CHEMOTHERAPY)				
NETUPITANT WITH PALONOSETRON Capsule 300 mg + 0.5 mg, 1	1	5		

Category / Program	GENERAL – General Schedule (Code GE)* Section 100 – Chemotherapy related benefits
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners* <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Nausea and vomiting
PBS Indication:	Nausea and vomiting
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

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Clinical criteria:	The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with dexamethasone; AND Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.
Prescriber Instructions	No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.
Administrative Advice	No increase in the maximum quantity or number of units may be authorised. No Increase in the maximum number of repeats may be authorised. This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

Category / Program	GENERAL – General Schedule (Code GE)* Section 100 – Chemotherapy related benefits
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners* <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Nausea and vomiting
PBS Indication:	Nausea and vomiting
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 condition must be associated with cytotoxic chemotherapy being used to treat breast cancer; AND The treatment must be in combination with dexamethasone; AND Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline;
Prescriber Instructions	No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.
Administrative Advice	No increase in the maximum quantity or number of units may be authorised. No Increase in the maximum number of repeats may be authorised. This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

9 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.

10 Sponsor's Comment

The sponsor had no comment.