nab-PACLitaxel Monotherapy– 21 day

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement Status*
Treatment of metastatic breast cancer in adult patients who have failed first-line treatment for metastatic disease and for whom standard, anthracycline containing therapy is not indicated.	C50	00230a	N/A

*This is for post 2012 indications

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patient's individual clinical circumstances.

nab-PACLitaxel is administered once every 21 days until disease progression or unacceptable toxicity develops, whichever occurs first. Discontinue treatment if no response after 2 cycles.

Facilities to treat anaphylaxis MUST be present when the systemic anti-cancer therapy (SACT) is administered.

Day	Drug	Dose	Route	Diluent & Rate	Cycle
1	nab-PACLitaxel	260mg/m^2	IV infusion	over 30 minutes	Repeat every 21 days

The use of medical devices containing silicone oil as a lubricant (i.e. syringes and IV bags) to reconstitute and administer nab-PACLitaxel may result in the formation of proteinaceous strands.

Administer nab-PACLitaxel using an infusion set incorporating a 15 µm filter to avoid administration of these strands. Use of a 15 µm filter removes strands and does not change the physical or chemical properties of the reconstituted product. If strands are present and a filter is not available, the product must be discarded.

nab-PAClitaxel is an albumin-bound nanoparticle formulation of PACLitaxel, which may have substantially different pharmacological properties compared to other formulations of PACLitaxel. It should not be substituted for or with other PACLitaxel formulations.

Note: Administration volumes and fluids have been standardised to facilitate electronic prescribing system builds.

ELIGIBILITY:

- Indications as above
- ECOG status 0-2

CAUTIONS:

- Grade ≥ 2 sensory or motor neuropathy

EXCLUSIONS:

- Hypersensitivity to nab-PACLitaxel, albumin, or to any of the excipients
- Baseline neutrophil count <1.5 x10^9/L
- Breastfeeding

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Medical Oncologist.

TESTS:

Baseline tests:

- FBC, renal and liver profile
- Assessment of cardiac function, e.g. ECG,ECHO/MUGA scan if significant cardiac history or previous anthracycline therapy

Regular tests:

- FBC, renal and liver profile prior to each cycle
- Cardiac function if clinically indicated

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- Any dose modification should be discussed with a Consultant.

Haematological:

Table 1: Dose modifications for neutropenia and/or thrombocytopenia

ANC ($x10^9$/L)		Platelets ($x10^9$/L)	Dose of nab-PACLitaxel
≥ 1.5	and	≥100	260mg/m^2
1-1.49	and	≥ 100	Delay 1 week and consider dose reduction 220mg
<1	OR	< 100	Delay until ANC≥ 1.5 $x10^9$/L and platelets ≥ 100 $x10^9$/L, then consider giving 220mg/m^2

Table 2: Dose modifications for febrile neutropenia

First Occurrence	Delay until recovery (ANC≥ 1.5 $x10^9$/L and platelets ≥ 100 $x10^9$/L), then dose reduce to **220mg/m^{2*}**
Second Occurrence	Delay until recovery (ANC≥ 1.5 $x10^9$/L and platelets ≥ 100 $x10^9$/L), then dose reduce to **180mg/m^{2*}**

*Dose reductions should be maintained for subsequent cycles and not re-escalated.

Renal and Hepatic Impairment:

Table 3: Dose modification of nab-PACLitaxel in renal and hepatic impairment

Renal Impairment		Hepatic Impairment	
CrCl (mL/min)	**Dose**	**Impairment level**	**Dose**
≥30	No dose adjustment is needed	Mild	No dose adjustment is needed
<30	No need for dose adjustment is expected.	Moderate and severe	Approximately 80% of original dose
Haemodialysis	No need for dose adjustment is expected.		
nab-PACLitaxel: Renal and hepatic dose modifications from Giraud et al 2023			

Management of adverse events:

Table 4: Dose Modifications for Adverse Events

Adverse reactions	Recommended dose modification
Grade ≥3 motor or sensory neuropathy First occurrence Second occurrence	 Hold treatment until resolved to grade 2 or less, then reduce dose to 220mg/m^2*** Hold treatment until resolved to grade 2 or less, then reduce dose to 180mg/m^2***
Grade 4 motor or sensory neuropathy First occurrence Second occurrence	 Hold treatment until resolved to grade 2 or less, then reduce dose to 220mg/m^2*** Discontinue OR Hold treatment until resolved to grade 2 or less, then reduce dose to 180mg/m^2***

***Dose reductions should be maintained for subsequent cycles and not re-escalated.

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

- As outlined in NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting- Available on the NCCP website

nab-PACLitaxel: Low **(Refer to local policy)**

For information:
Within NCIS regimens, antiemetics have been standardised by Medical Oncologists and Haemato-oncologists and information is available in the following documents:

- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Medical Oncology) - Available on the NCCP website
- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Haemato-oncology) - Available on the NCCP website

PREMEDICATIONS: None usually required.

OTHER SUPPORTIVE CARE:
Myalgias and arthralgias may occur with nab-PACLitaxel. Analgesic cover should be considered.

ADVERSE EFFECTS

- Please refer to the relevant Summary of Product Characteristics (SmPC) for details.

DRUG INTERACTIONS:

Current SmPC and drug interaction databases should be consulted for information

REFERENCES:

1. Gradishar WJ et al. Phase III trial of nanoparticle albumin-bound paclitaxel compared with polyethylated castor oil-based paclitaxel in women with breast cancer. J Clin Oncol 2005;23(31):7794-803
2. BCCA Protocol Summary for Palliative Therapy for Metastatic Breast Cancer using PACLitaxel-NAB (ABRAXANE®) BRAVABR October 2016.
3. MHRA, Drug Safety Update, Abraxane (paclitaxel, formulated as albumin-bound nanoparticles): potential presence of strands in intravenous infusion bag—if visible, filtration advised. February 2014. Available at: https://www.gov.uk/drug-safety-update/abraxane-paclitaxel-formulated-as-albumin-bound-nanoparticles-potential-presence-of-strands-in-intravenous-infusion-bag
4. Giraud E L, Lijster B D, et al. Dose recommendations for anticancer drugs in patients with renal or hepatic impairment: an update. Available at: https://pubmed.ncbi.nlm.nih.gov/37269847/
5. NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting. V6 2025. Available at: https://www.hse.ie/eng/services/list/5/cancer/profinfo/chemoprotocols/nccp-classification-document-for-systemic-anti-cancer-therapy-sact-induced-nausea-and-vomiting.pdf
6. Abraxane® (nab-PACLitaxel) Summary of Product Characteristics. Last updated: 30/01/2025. Accessed March 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/abraxane-epar-product-information_en.pdf
7. Pazenir® (nab-PACLitaxel) Summary of Product Characteristics. Last updated: 30/08/2024. Accessed March 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/pazenir-epar-product-information_en.pdf

Version	Date	Amendment	Approved By
1	05/04/2014		Prof Maccon Keane
2	29/04/2014	Updated advice on filters for administration	Prof Maccon Keane
3	08/04/2016	Updated dose modifications in renal and hepatic impairment and for adverse reactions (Table 1) as per SmPC	Prof Maccon Keane
4	18/04/2018	Updated with new NCCP regimen template, Updated hepatoxicity adverse events as per SmPC	Prof Maccon Keane
5	29/04/2020	Reviewed.	Prof Maccon Keane
6	24/02/2022	Brand name Abraxane® removed. ATC codes removed. Updated reference section.	Prof Maccon Keane
7	01/04/2025	Reviewed. Updated exclusions section. Added cautions section.Updated table 3 with Giraud et al 2023	Prof Maccon Keane

		recommendations. Updated regimen in line with NCCP standardisation.	

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.