Regimen Monograph

A - Regimen Name

NPAC Regimen

nab-PACLitaxel

Disease Site

Genitourinary
Bladder / Urothelial

Intent

Palliative

Regimen Category

Evidence-Informed :

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

Rationale and Uses

For second-line treatment of locally advanced or metastatic urothelial bladder cancer after failure of a platinum-containing regimen.

NDFP funding is available for eligible patients who experienced hypersensitivity reactions to taxanes or have significant contraindications to taxanes and/or their pre-medications.

(Refer to the NDFP eligibility form for detailed funding criteria.)

Supplementary Public Funding

nab-PACLitaxel
New Drug Funding Program (Nab-Paclitaxel - Hypersensitivity Reactions to Taxanes) (NDFP Website)

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B - Drug Regimen

Nab-PACLitaxel is not-interchangeable with other PACLitaxel formulations.

nab-PACLitaxel	260 mg /m²	IV	Day 1

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

Until disease progression or unacceptable toxicity.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low (No premedication to prevent hypersensitivity is required.)

- Also refer to CCO Antiemetic Summary

Screen for hepatitis B virus in all cancer patients starting systemic treatment. Refer to the hepatitis B virus screening and management guideline.

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated. The following recommendations have been adapted from clinical trials or product monographs and could be considered.

Nab-PACLitaxel is not-interchangeable with other PACLitaxel formulations.

Do not retreat until recovery from toxicity and neutrophils ≥ 1.5 x 10^9/L and platelets ≥ 100 x 10^9/L.

Dosage with toxicity

Worst Toxicity / Counts (x10^9/L) in previous cycle	**Dose (mg/m^2) Every 3 Weeks**		
	First occurrence	Second occurrence	Third Occurrence
ANC < 0.5 ≥ 7 days or Febrile neutropenia or Grade 4 platelets or bleeding	*220 mg/m^2	*180 mg/m^2	Discontinue
Grade 3 or 4 sensory neuropathy or other grade 3 related organ toxicity	*220 mg/m^2 OR consider discontinuing for Grade 4 neurotoxicity	*180 mg/m^2 OR consider discontinuing for Grade 4 neurotoxicity	Discontinue
Other grade 4 related organ toxicity; severe hypersensitivity, cystoid macular edema	Discontinue	Discontinue	Discontinue
Pneumonitis	Hold and investigate; discontinue if confirmed	n/a	n/a
* Do not retreat until ANC ≥ 1.5 x 10^9/L, platelets ≥ 100 x 10^9/L and other toxicity ≤ grade 2.			

Hepatic Impairment

Patients with hepatic impairment may be at increased risk of myelosuppression and should be closely monitored. Nab-paclitaxel is not recommended in patients with metastatic pancreatic cancer who have moderate to severe hepatic impairment.

Bilirubin		**AST**	**Nab-paclitaxel*** **(% previous dose - suggested)**
>1 to ≤ 1.5 x ULN	and	≤ 10 x ULN	100%
>1.5 to ≤ 5 x ULN	and	≤ 10 x ULN	↓ to 80%
> 5 x ULN	or	> 10 x ULN	Discontinue

*Based on clinical judgment – less conservative adjustments can be considered if hepatic changes are secondary to metastases rather than hepatic cirrhosis or hepatitis. Patients with elevated baseline bilirubin were excluded from clinical trials.
**Reduced dose may be escalated to 100% if treatment is tolerated for at least 2 cycles at the reduced dose.

Renal Impairment

Creatinine Clearance (mL/min)	**Nab-paclitaxel*** **(% previous dose - suggested)**
≥ 30 to < 90	100%
< 30	Discontinue

* Based on clinical judgment. Patients with elevated baseline creatinine were excluded from clinical trials.

Dosage in the Elderly

No dose adjustment is required. Patients age 65 years or older may have higher incidence of neutropenia in cycle 1. Patients aged 65 and older who received nab-paclitaxel monotherapy for metastatic breast cancer had a higher incidence of epistaxis, diarrhea, dehydration, fatigue and peripheral edema.

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F - Adverse Effects

Refer to nab-PACLitaxel drug monograph(s) for additional details of adverse effects.

Very common (≥ 50%)	Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Alopecia • Sensory neuropathy (may be severe)	• Fatigue • Musculoskeletal pain • Increased LFTs (may be severe) • Nausea, vomiting • Diarrhea (may be severe)	• Edema • Cough, dyspnea • Constipation • Myelosuppression +/- infection, bleeding (may be severe) • Rash (may be severe) • Increased creatinine (may be severe)	• Injection site reaction • Hypersensitivity • Cardiotoxicity • Arrhythmia • Autonomic neuropathy • Arterial/venous thromboembolism • Hemolytic uremic syndrome, TTP • GI obstruction, perforation • Pancreatitis • Pneumonitis • Keratitis, cystoid macular edema

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G - Interactions

Refer to nab-PACLitaxel drug monograph(s) for additional details.

No drug interaction studies have been conducted with nab-paclitaxel, but are likely to be similar to those reported for paclitaxel (refer to the paclitaxel drug monograph).

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H - Drug Administration and Special Precautions

Refer to nab-PACLitaxel drug monograph(s) for additional details.

Administration

- Refer to the product monograph for full instructions on reconstitution.
- The reconstituted suspension should be milky and homogenous without visible particulates.
- Avoid shaking drug suspension in order to minimize foaming.
- No further dilution is required after reconstitution. Transfer reconstituted drug to an empty, sterile IV PVC or non-PVC infusion bag.
- Infuse intravenously over 30 minutes. Slower infusion rates may increase the likelihood of infusion-related reactions.
- DEHP-free containers or administration sets may be used but are not required.
- Do not admix with other drugs.
- Use of syringes and IV bags containing silicone oil as lubricant may cause formation of proteinaceous strands. If strands are observed by visual inspection of IV bag, administer reconstituted suspension through filter of at least 15 µm pore size. If this is not possible, discard the product.

Contraindications

- Patients who have a hypersensitivity to this drug or any of its components (such as albumin) in the formulation or container
- Patients with baseline ANC of < 1.5 x 10^9/L or platelets < 100 x 10^9/L on day 1 of each treatment cycle
- Patients with a history of interstitial lung disease, multiple allergies, progressive dyspnea or unproductive cough

Warnings/precautions

- The use of albumin-containing solutions is associated with a remote risk of viral transmission, including CJD.
- Radiation recall and pneumonitis have been reported in patients with concurrent radiotherapy.
- Caution is recommended prior to driving or operating machinery if fatigue or dizziness are present.

Pregnancy and lactation

- Nab-paclitaxel is not recommended for use in pregnancy. Adequate contraception should be used by both sexes during treatment and for at least 6 months after the last dose.
- Breastfeeding is not recommended.

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I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Refer to the hepatitis B virus screening and management guideline for monitoring during and after treatment.

Recommended Clinical Monitoring

- CBC; baseline and before each cycle
- Liver function tests; baseline and regular
- Clinical toxicity assessment of neuropathy, infection, hypersensitivity, musculoskeletal, GI, ophthalmic, thromboembolism, local reactions and pneumonitis; at each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- ECG; as clinically indicated for patients at risk of arrhythmia

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J - Administrative Information

Approximate Patient Visit	1 hour
Pharmacy Workload (average time per visit)	32.929 minutes
Nursing Workload (average time per visit)	35 minutes

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K - References

Ko Y, Canil CM, Mukherjee SD, et al. Nanoparticle albumin-bound paclitaxel for second-line treatment of metastatic urothelial carcinoma: a single group, multicentre, phase 2 study. Lancet Oncol 2013; 14: 769–76.

Nab-paclitaxel drug monograph, Ontario Health (Cancer Care Ontario).

December 2024 Added NDFP form; updated Rationale/uses and Drug Regimen sections

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Regimen Monographs

Refer to the New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public funding information.

The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

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Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

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