

## Nab-Paclitaxel - Hypersensitivity Reactions to Taxanes

(This form should be completed before the first dose is dispensed.)

### 1. Patient Profile

- \* Surname: .....
- \* Given Name: .....
- \* OHIN: ..... \* Chart Number: .....
- \* Postal Code: .....
- \* Height (cm): ..... \* Weight (kg): .....
- \* BSA (m<sup>2</sup>): ..... \* Gender:  Male  Female  Other
- \* Date of Birth: .....  
Day    Month    Year
- \* Site: .....
- \* Attending Physician (MRP- Most Responsible Physician): .....
- Requested Prior Approval  Yes    \* Patient on Clinical Trial:  Yes  No
- Specify trial: .....
- Specify Arm:  
 Standard of care arm                       Experimental arm  
 Blinded / Unknown

### Prior Approval Request

\* Select the appropriate prior approval scenario:

- 1-Unknown primary (submit pathology report and clinic note)
- 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below)
- 3-Regimen modification - schedule (complete questions a and b)
- 4-Regimen modification - drug substitutions (complete questions a and c)
- 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f)
- 6-Maintenance therapy delay (submit clinic note)
- 7-Prior systemic therapy clinical trials (complete question g)
- 8-Modification due to supply interruption/drug shortage
- Other (specify)

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**All relevant supporting documentation must be submitted at the time of prior approval. Documentation may include a pathology report, clinic note, and/or CT scans.**

a. Co-morbidities / toxicity / justification:

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b. Intended regimen schedule:

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c. Intended regimen:

.....

d. Drug(s) to be held:

.....

e. Rationale for holding drug(s):

.....

f. Intention to introduce drug at a later date?

Yes

g. Prior clinical trial identifier (e.g., NCT ID, trial name) and treatment description (e.g., arm, drug/regimen):

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h. Anticipated date of first treatment:

..... Day    Month    Year

i. Additional comments:

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## 2. Eligibility Criteria

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Nab-paclitaxel will be used for the treatment of patients who meet at least one of the following criteria (please select all that apply):

- Experienced a grade 2 or 3 moderate to severe hypersensitivity reaction(s) to a taxane that may not be manageable despite the use of pre-medications and infusion prolongation
- Experienced an anaphylaxis or anaphylactoid reaction to a taxane
- Have significant contraindications to taxanes and/or their pre-medications

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## 3. Baseline Information

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a. Is the patient being treated in the curative or palliative setting?       Curative       Palliative

b. If "curative" selected under 3a, for which indication is the patient being treated?

- Breast cancer       Non-small cell lung cancer
- Upper GI (esophageal, esophagogastric, gastric) cancer
- Cervical Cancer       Endometrial cancer
- Ovarian, fallopian tube, or primary peritoneal cancer
- Germ cell, testicular or prostate cancer       Bladder cancer
- Other

If "other", please specify .....

c. If "palliative" selected under 3a, for which indication is the patient being treated?

- Non-small cell lung cancer
- Upper GI (esophageal, esophagogastric, gastric) cancer [for pancreatic, refer to note 4]
- Lower GI (small bowel, appendiceal, colorectal, anal) cancer
- Cervical Cancer       Endometrial cancer
- Ovarian, fallopian tube, or primary peritoneal cancer
- Germ cell, testicular or prostate cancer       Vulvar cancer
- Bladder cancer       Thyroid cancer
- Head and Neck Cancer
- Sarcoma - Soft tissue or Kaposi's       Melanoma
- Other

If "other", please specify .....

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## 4. Funded Dose

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Nab-paclitaxel 80 – 260\* mg/m<sup>2</sup> given intravenously (IV) once every one to three weeks.

\* Dosing and frequency are dependent on the protocol by which the patient is being treated.

Treatment should continue until disease progression or unacceptable toxicity, whichever comes first.

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## 5. Notes

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1. Patients with metastatic breast cancer will continue to use the disease-specific policy, “Nab-Paclitaxel - Metastatic Breast Cancer”.
2. Patients with advanced pancreatic cancer will continue to use the disease-specific policy, “Gemcitabine and Nab-Paclitaxel - Advanced Pancreatic Cancer”.

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## 6. FAQs

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### Supporting Documents

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None required at time of enrolment.

In the event of an audit or upon request, the following should be available to document eligibility:

- Clinic notes outlining patient and treatment history/response.
- Clinic note(s) describing the grade 2 or 3 hypersensitivity reaction(s) to a taxane, anaphylaxis or anaphylactoid reaction(s) to a taxane, or the significant contraindications to a taxane and/or their premedication.
- CT scans demonstrating no disease progression while on treatment.

Signature of Attending Physician (MRP-Most Responsible Physician): .....

.....  
Day      Month      Year