Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Nivolumab - Neoadjuvant Treatment for Non-Small Cell Lung Cancer

(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^2): .....

* 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

Other (specify): .....

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)

.....

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:

b. Intended regimen schedule:

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):

h. Anticipated date of first treatment: Day Month Year

i. Additional comments:

2. Eligibility Criteria

Nivolumab is used in combination with platinum-doublet chemotherapy for the neoadjuvant treatment of adult patients with resectable non-small cell lung cancer (NSCLC). ☐ Yes

Patients must have:

- Tumours that are 4 cm or greater in size or are node positive AND
- A good performance status.

Patients must not have any of the following:

- N3 disease,*
- Known *EGFR* or *ALK* gene abnormalities,
- Large cell neuroendocrine carcinoma tumour histology,
- Unresectable or metastatic disease.

* Based on the American Joint Committee on Cancer (AJCC), 8th edition.

3. Baseline Information

a. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2

b. Is the patient transitioning from a private pay or compassionate program? ○ Yes ○ No

c. If yes, please indicate the funding source
○ Private payer
○ Manufacturer patient support program

d. If yes, please indicate the date of the last administered dose Day Month Year

e. If yes, how many previous treatments did the patient receive?

○ N/A ○ 1 ○ 2

4. Funded Dose

Nivolumab 4.5 mg/kg intravenously (IV) (up to a maximum of 360 mg) every 3 weeks.

Treatment should continue until disease progression, unacceptable toxicity, or completion of 3 cycles of neoadjuvant nivolumab, whichever comes first.

[ST-QBP regimen code(s): CISPVINO+NIVL, CISPGEMC+NIVL, CISPPEME+NIVL, CRBPPEME+NIVL, CRBPPACL+NIVL]

5. Notes

1. Patients who are not eligible for initiation of platinum-based neoadjuvant chemotherapy and/or surgical resection are ineligible for nivolumab funding.

6. FAQs

1. **My patient is currently receiving nivolumab through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding for nivolumab through the New Drug Funding Program (NDFP)?**

   Provided the eligibility criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for continued coverage through the NDFP.

2. **What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?**

   If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

   Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:
   - A clinic note and imaging (if applicable) from treatment initiation, AND
   - The most recent clinic note and imaging (if applicable).

   Based on recommendations from the Canadian Agency for Drugs and Technologies in Health (CADTH), Ontario Health (Cancer Care Ontario) does not reimburse hospitals for nivolumab given as a fixed or flat dose under this policy. Regardless of the patient's prior funding source or prior dosing, the NDFP will fund the weight-based dosing as indicated in the Funded Dose section above.

3. **My patient cannot tolerate their current chemotherapy regimen that includes nivolumab. Can my patient continue with single agent nivolumab?**

   Patients who experience intolerance attributed to the chemotherapy portion of their regimen may continue nivolumab alone to a maximum of 3 doses.

4. **My patient completed neoadjuvant nivolumab therapy and received a complete resection, but subsequently recurred with advanced disease. What treatment options are available?**

   Patients who experience disease recurrence will be able to access first-line immunotherapy in the advanced or metastatic setting (e.g., pembrolizumab with or without chemotherapy, nivolumab plus ipilimumab with chemotherapy), provided all eligibility criteria are met.

7. Supporting Documents

None required at time of enrolment.

In the event of an audit or upon request, the following should be available to document eligibility:
- Pathology report documenting NSCLC histology and absence of EGFR or ALK mutations.
- Clinic note(s) and imaging documenting disease staging.

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

....
Day Month Year

Form 1037