Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Nivolumab plus Ipilimumab - In Combination with Platinum Doublet Chemotherapy for First Line Metastatic or Recurrent 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

The patient must meet the following criteria:

Nivolumab plus ipilimumab is used in combination with two cycles of platinum doublet chemotherapy (PDC) for the first line treatment of adult patients with metastatic or recurrent non-small cell lung cancer (NSCLC) with no known epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumour aberrations, and who have good performance status.

☐ Yes

3. Baseline Information

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

b. Disease Stage
- ○ Stage 4
- ○ Stage 3 NSCLC but not a candidate for curative treatment
- ○ Non-metastatic or recurrent NSCLC but not amenable to radical treatment

c. Tumour histologic type
- ○ Squamous ○ Non-squamous
- ○ Large cell neuroendocrine tumour that is being treated with a NSCLC regimen
- ○ Uncommon NSCLC subtype that is being treated with a NSCLC regimen

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

e. If yes, how many doses of q3weekly nivolumab did the patient have prior to transitioning to public funding?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9
○ 10	○ 11	○ 12	○ 13	○ 14	○ 15	○ 16	○ 17	○ 18
○ 19	○ 20	○ 21	○ 22	○ 23	○ 24	○ 25	○ 26	○ 27
○ 28	○ 29	○ 30	○ 31	○ 32	○ 33	○ 34		

f. If yes, how many doses of q6weekly ipilimumab did the patient have prior to transitioning to public funding?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9
○ 10	○ 11	○ 12	○ 13	○ 14	○ 15	○ 16	○ 17	

4. Funded Dose

Nivolumab 4.5 mg/kg intravenously (IV), up to a maximum of 360 mg, every 3 weeks plus ipilimumab 1 mg/kg IV every 6 weeks.

Nivolumab plus ipilimumab must be given in combination with 2 cycles of platinum doublet chemotherapy, followed by maintenance nivolumab plus ipilimumab until confirmed disease progression or unacceptable toxicity up to a maximum of 2 years, whichever comes first.

(ST-QBP regimen codes: One of CISPPEME+NIVL+IPIL, CRBPPACL+NIVL+IPIL, CRBPPEME+NIVL+IPIL, CRBPGEMC+NIVL+IPIL or CISPGEMC+NIVL+IPIL for the induction phase, followed by NIVL+IPIL(MNT) for the maintenance phase.)

5. Notes

1. Ontario Health (Cancer Care Ontario) will fund one line of atezolizumab, nivolumab, nivolumab plus ipilimumab, or pembrolizumab for advanced non-small cell lung cancer.
2. Patients who were treated with durvalumab (or other anti-PD1/PD-L1 therapy) in the curative setting must have a disease free interval of 6 months or greater in order to be considered for funding under this policy.
3. For patients who stop nivolumab plus ipilimumab without disease progression, continuation of nivolumab plus ipilimumab (to complete 2 years' worth of treatment) will be funded provided that no other treatment is given in between.
4. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 years' worth of nivolumab plus ipilimumab treatment at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same enrolment form used for initial treatment.
5. Nivolumab plus ipilimumab will not be funded if the patient has a typical or atypical carcinoid tumour.

6. FAQs

i. **My patient is currently receiving nivolumab plus ipilimumab through non-publicly funded means. Can my patient be transitioned over to receive funding through the New Drug Funding Program (NDFP)?**

Provided the funding 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 of nivolumab plus ipilimumab through NDFP. Please submit as a prior approval request including the most recent clinic note documenting the response to treatment, if able to assess, and number of cycles of nivolumab plus ipilimumab received to date.

At the NDFP funded dose of nivolumab 4.5 mg/kg, up to a maximum of 360 mg every 3 weeks, and ipilimumab 1 mg/kg every 6 weeks, funding is for a total of 2 years' worth of treatment for the initial course, regardless of the funding source.

ii. **My patient may not be able to tolerate both nivolumab plus ipilimumab and platinum doublet chemotherapy upfront. Can I start my patient with nivolumab plus ipilimumab and add the other part later?**

The patient must receive nivolumab plus ipilimumab with a platinum doublet at the start of therapy in order to be eligible for nivolumab plus ipilimumab.

iii. **My patient is currently on the 2nd cycle of platinum-doublet chemotherapy for first line metastatic non-small cell lung cancer. Can I add nivolumab plus ipilimumab to the treatment regimen?**

In the scenario where an immunotherapy-eligible patient has only received 1 to 2 cycles of platinum-doublet chemotherapy, it may be reasonable to offer two additional cycles of platinum doublet chemotherapy when initiating treatment with nivolumab plus ipilimumab.

iv. **My patient experienced a major toxicity from the initial cycle of platinum doublet chemotherapy. Will NDFP fund the continuation of nivolumab plus ipilimumab without the chemotherapy?**

Patients who discontinue chemotherapy due to a major toxicity are eligible to receive nivolumab plus ipilimumab until confirmed disease progression or unacceptable toxicity up to a maximum of 2 years, whichever comes first.

v. **My patient had to discontinue ipilimumab due to an adverse event. Will NDFP fund the continuation of nivolumab as a single agent?**

Patients who discontinue ipilimumab due to a significant adverse event are eligible for continued funding of nivolumab (as monotherapy) on this policy.

vi. **My patient is being treated with a non-platinum-based regimen. Will NDFP fund the addition of nivolumab plus ipilimumab?**

Nivolumab plus ipilimumab will not be funded if used in combination with either a non-platinum-based regimen or with single agent chemotherapy.

Supporting Documents

None required at the time of enrolment.

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

- CT scans every 3 to 6 months, along with clinic notes indicating no disease progression.
- In instances where there is pseudoprogression, a clinic note documenting the assessment and decision to continue, and the subsequent CT scan confirming no disease progression.

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

....
Day Month Year

Form 937