Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Nivolumab - Advanced or Metastatic Non-Small Cell Lung Cancer

(This form must 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
- ○ 9-Supplemental doses requested
- ○ 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:

.....

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 is used as a treatment for adult patients with advanced or metastatic non-small cell lung cancer (NSCLC) with disease progression on or after cytotoxic chemotherapy for advanced disease and who have a good performance status. ☐ Yes

3. Baseline Information

a. ECOG performance status at the time of enrolment ○ 0 ○ 1 ○ 2

b. Disease stage ○ Stage 3B ○ Stage 4

c. Tumour histologic type ○ Squamous ○ Non-squamous ○ Not otherwise specified (NOS)

d. Mutational status ○ ALK-positive ○ EGFR-positive ○ ALK and EGFR-negative

e. PD-L1 expression level ○ Not tested ○ 0 ○ 1-49% ○ Greater than or equal to 50%

f. Has the patient received any of the following drugs for advanced lung cancer: docetaxel, gemcitabine, paclitaxel, pemetrexed or vinorelbine? ○ Yes ○ No

g. Nivolumab is being given as the ____ line of treatment. (Note: Platinum-doublet followed by pemetrexed maintenance constitutes as one line of treatment.) ○ 2nd ○ 3rd ○ 4th line or greater

4. Funded Dose

- Nivolumab 3 mg/kg IV, up to a maximum dose of 240 mg, every 2 weeks as an intravenous infusion, or nivolumab 6 mg/kg IV, up to a maximum dose of 480 mg, every 4 weeks as an intravenous infusion.

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. 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.
2. It is recommended that nivolumab be used after treatment with a platinum-based therapy.
3. The patient is no longer eligible for nivolumab once there is confirmed disease progression.
4. If the patient previously received non-NDFP funded chemotherapy for NSCLC, clarification (documented in a clinic note) may be requested to confirm the patient's prior chemotherapy treatments.
5. Nivolumab funding is for single agent use only.

6. FAQs

i. **My patient is currently receiving nivolumab through private 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 through the New Drug Funding Program.

ii. **My patient is currently on single agent docetaxel. Can my patient still access nivolumab?**

   The funding rules for nivolumab specify use in patients with disease progression on or after cytotoxic chemotherapy for advanced disease and who have good performance status.

iii. **My patient is currently receiving nivolumab on an every 2 week schedule. Can my patient be transitioned over to the every 4 week schedule?**

   The decision to switch should be based on a discussion between the clinician and patient. Switches between schedules (from every 2 weeks to every 4 weeks or vice versa) will be eligible for continued funding provided the patient's disease has not progressed.

iv. **What is the rationale for having a maximum dose for the every 2 week schedule?**

   Exposure-response relationships for efficacy and clinical safety have shown that the benefit-risk profile is comparable between weight-based dosing and the 240 mg flat dose. Weight-based dosing, up to a maximum dose, will be applied across all nivolumab policies and is in alignment with other Canadian jurisdictions who have implemented nivolumab.

v. **My patient is currently on the every 2 week schedule at a dose greater than 240 mg. Will this dose continue to be eligible for funding?**

   On a time-limited basis (until November 2, 2018), CCO will allow funding for doses greater than 240 mg for patients who initiated treatment with the 3 mg/kg every 2 week schedule prior to September 7, 2018. This time-limited funding allows clinicians an opportunity to inform patients of the revised dosing schedule, and to update their computerized prescriber order entry (CPOE) systems accordingly. Starting November 3, 2018, reimbursement will be capped at 240 mg for the every 2 week schedule. Patients who switch to the 6 mg/kg every 4 week schedule are required to adhere to the maximum dose of 480 mg as of the effective funding date.

vi. **My patient is currently on a 'treatment break' and requires resumption of their nivolumab therapy. If their original dose exceeded 240 mg, are clinicians required to adopt the maximum dose cap?**

   Upon resumption of therapy, patients on a 'treatment break' will be required to adhere to the funded dose for any dose(s) given after November 2, 2018 (e.g., 3 mg/kg, up to 240 mg, every 2 weeks or 6 mg/kg, up to 480 mg, every 4 weeks).

7. Supporting Documents

None required for this policy.

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
    - a confirmatory scan conducted preferably at 6 to 8 weeks but no later than 12 weeks after the initial disease progression to confirm the absence of true progression.

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

....
Day Month Year

Form 939