Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - Advanced or Metastatic Non-Small Cell Lung Cancer (Second or Subsequent Line)

(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)

.....

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:

- Pembrolizumab is used for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumours express PD-L1 with Tumour Proportion Score (TPS) ≥ 1% (as determined by a validated test) and who have good performance status, and who have disease progression on or after cytotoxic chemotherapy. ☐ Yes
- Patients with epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genetic tumour aberrations should have disease progression on authorized therapy for these aberrations and cytotoxic chemotherapy prior to receiving pembrolizumab.

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 ○ 1-49% ○ >=50%

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

g. Pembrolizumab 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

Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or
Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days.

Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first.

[ST-QBP regimen code: PEMB]

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. Patients who complete 35 cycles without disease progression may receive up to additional 17 cycles at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same form used for initial treatment.
3. It is recommended that pembrolizumab be used after treatment with a platinum-based therapy.
4. Patients switching from other therapies for second or subsequent line NSCLC must provide PD-L1 testing results and a clinic note indicating the reason for switching when submitting the enrolment form.
5. Pembrolizumab is not funded for patients who have confirmed disease progression after receiving a prior anti-PD-1 inhibitor in the metastatic setting.
6. Pembrolizumab funding is for single agent use only.

6. FAQs

i. **My patient is currently receiving pembrolizumab 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 pembrolizumab through the New Drug Funding Program. Note that the patient will be eligible for a total of 2 years (35 doses) for initial treatment, regardless of the funding source.

ii. **My patient would like to switch from nivolumab or other second line therapies (e.g. docetaxel, single agent pemetrexed) to pembrolizumab. Will this be funded?**

For a time-limited basis (ending July 17, 2018), CCO will allow patients to switch from nivolumab to pembrolizumab, as long as there has not been disease progression on nivolumab. Sites must submit the enrolment for pembrolizumab along with supporting documentation (i.e., CT scans indicating stable disease on nivolumab, clinic note indicating the reason for switching). Note that patients who switch from nivolumab to pembrolizumab will be eligible for a total of 2 years of anti-PD-1 treatment (nivolumab and pembrolizumab combined).

Patients who are switching from other second line therapies (e.g. docetaxel, single agent pemetrexed) must not have experienced disease progression on the current treatment. Sites must submit the enrolment for pembrolizumab along with supporting documentation (i.e., CT scans indicating stable disease on current treatment, clinic note indicating the reason for switching).

iii. **My patient has progressed on nivolumab treatment or had to discontinue nivolumab due to unacceptable toxicity. Will subsequent treatment with pembrolizumab be funded by NDFP?**

Ontario Health (Cancer Care Ontario) will fund one line of anti-PD-1 therapy for patients with advanced metastatic non-small cell lung cancer (i.e., one of pembrolizumab first line, pembrolizumab second or subsequent line, nivolumab plus ipilimumab first line, or nivolumab second or subsequent line).

iv. **My patient is currently receiving pembrolizumab on an every 3 week schedule. Can my patient be transitioned over to an every 6 week schedule?**

The decision to switch should be based on a discussion between the clinician and patient. Switches between schedules (from every 3 weeks to every 6 weeks or vice versa) will be eligible for continued funding provided the patient's disease has not progressed. Please note that the funded duration remains the same (i.e., a maximum of two years for the initial treatment course plus one additional year of retreatment, if eligible).

7. Supporting Documents

None required.

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

- PD-L1 testing results indicating Tumour Proportion Score (TPS) $\geq$ 1% as determined by a validated test.
- 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 954