Ontario Health | Santé Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

Pembrolizumab - (Neo)Adjuvant Therapy for Resectable 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

Pembrolizumab will be used for the treatment of adult patients with resectable early-stage non-small cell lung cancer (NSCLC) in combination with platinum-containing chemotherapy as neoadjuvant treatment, and as maintenance in the adjuvant setting.

☐ Yes

Patients must have:

- Stage II to IIIB (N2)* disease
- A good performance status

Patients must not have:

- N3* disease
- Known EGFR or ALK gene abnormalities
- Prior immune checkpoint inhibitor therapy

*Based on the American Joint Committee on Cancer TNM staging system, 9th edition.

3. Baseline Information

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

b. Tumour histologic type
○ Squamous ○ Non-Squamous

c. Disease stage
○ Stage IIA ○ Stage IIB ○ Stage IIIA
○ Stage IIIB (N2)

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

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

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

g. If yes, how many doses of pembrolizumab given every 3 weeks did the patient receive prior to the transition?
○ N/A ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11
○ 12 ○ 13 ○ 14 ○ 15 ○ 16

h. If yes, how many doses of pembrolizumab given every 6 weeks did the patient receive prior to the transition?

○ N/A ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
○ 6 ○ 7 ○ 8

4. Funded Dose

In the neoadjuvant setting:
Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 3 weeks in combination with platinum-based chemotherapy for 4 cycles.

In the adjuvant setting:
Pembrolizumab 2 mg/kg IV (up to a maximum of 200 mg) every 3 weeks, or 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks until disease progression or unacceptable toxicity.

Funding is for a total maximum duration of 1 year or equivalent (i.e., 17 cycles of every 3-week dosing, or 9 cycles of every 6-week dosing), whichever comes first.

[ST-QBP regimen code(s): CRBPPACL+PEMB, CISPGEMC+PEMB, CISPPEME+PEMB, CRBPGEMC+PEMB, CRBPPEME+PEMB for the neoadjuvant portion, followed by PEMB for the adjuvant portion]

5. Notes

1. Patients who are not eligible for surgical resection and initiation of neoadjuvant platinum-based chemotherapy are ineligible for pembrolizumab funding under this policy.

2. Patients who experience intolerable toxicity attributable to the neoadjuvant platinum-based chemotherapy may continue with pembrolizumab.

3. Patients treated with an immune checkpoint inhibitor in the curative setting who have a disease-free interval of 6 months or greater from the last dose may be eligible for one line of PD-1/PD-L1 inhibitor therapy for advanced NSCLC, provided all other eligibility criteria are met.

6. FAQs

1. **My patient is currently receiving pembrolizumab through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding 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:
   - Clinic note(s) documenting tumour staging and use of platinum-based neoadjuvant chemotherapy.
   - Surgical pathology report(s) documenting a complete resection, if applicable.
   - CT scans demonstrating no disease progression, if applicable.

   Please note: Patients who meet the NDFP eligibility criteria and are enrolled in the manufacturer's patient support program (PSP) are eligible to receive continued drug supply through the PSP until October 24, 2025, inclusive.

   After this date, patients who met the NDFP eligibility criteria at the point of treatment initiation are eligible to transition to NDFP funding for the remainder of their treatment course. Although sites may enroll their patient onto this policy at any time beforehand, any treatment claims submitted to eClaims that were given on or before the PSP transition date will be denied.

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

   The NDFP will fund a total duration of 1 year (or equivalent), regardless of funding source.

3. **My patient completed neoadjuvant nivolumab with chemotherapy and underwent a complete resection. Is my patient eligible for adjuvant pembrolizumab under this policy?**

   If no disease progression has occurred and provided all eligibility criteria are met, adjuvant pembrolizumab is a funded option.

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:
- Clinic note(s) documenting tumour staging and use of platinum-based neoadjuvant chemotherapy.
- Surgical pathology report(s) documenting a complete resection.
- CT scans demonstrating no disease progression.

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

Day Month Year

Form 1108