Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab (Adult and Pediatric) - Adjuvant Treatment for Completely Resected Stage IIB or IIC Melanoma

(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
○ 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 is used in the adjuvant treatment of adult and pediatric (12 years and older) patients with stage IIB or IIC* melanoma following complete resection. ☐ Yes

Treatment is only for patients who have not received previous systemic treatment for melanoma and have good performance status (PS).

Treatment with pembrolizumab should be initiated within 12 weeks of surgery.

*As defined by the American Joint Committee on Cancer 2017 classification, eighth edition.

3. Baseline Information

a. ECOG Performance Status at the time of enrolment: ○ 0 ○ 1 ○ 2 ○ Not applicable

b. Karnofsky (for patients 16 years old and older) or Lansky (for patients under 16 years old) PS for pediatric patients: ○ 50 ○ 60 ○ 70 ○ 80 ○ 90 ○ 100 ○ Not applicable

c. Disease stage ○ IIB ○ IIC

d. BRAF V600 mutation status ○ Positive ○ Negative ○ Unknown

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

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

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

h. 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

i. 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

Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 3 weeks (adult and pediatric),
or
Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks (adult patients only).

Treatment should continue until disease progression, or unacceptable toxicity, up to a maximum of 12 months (or equivalent therapy*), whichever comes first.

*17 cycles if administered every 3 weeks, or 9 cycles administered every 6 weeks.

[ST-QBP regimen code(s): PEMB]

5. Notes

1. Pembrolizumab funding is for single agent use only.

2. Patients with ocular melanoma will not be eligible for adjuvant pembrolizumab.

3. Patients who have confirmed disease progression on adjuvant nivolumab or pembrolizumab will not be eligible for anti-PD-1 or anti-PD-L1 immunotherapy in the metastatic setting. However, these patients may be eligible for single agent ipilimumab.

4. Patients whose disease recurs at least 6 months after their last dose of adjuvant nivolumab or pembrolizumab for stage IIB-IIC disease may be eligible for adjuvant nivolumab or (neo)adjuvant pembrolizumab for stage III-IV completely resectable disease.

5. Patients whose disease relapses at least 6 months after their last dose of adjuvant nivolumab or pembrolizumab may be eligible for combination ipilimumab and nivolumab in the metastatic setting. If the patient is unfit for combination immunotherapy, they may be eligible for single agent immunotherapy.

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 for pembrolizumab 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 of pembrolizumab through the NDFP.

   Patients who meet the eligibility criteria may be transitioned to NDFP funding through a regular eClaims enrolment. If there is clinical uncertainty regarding eligibility, these requests may be submitted as a prior approval including a clinic note from the time of initiation as well as the most recent clinic note outlining the response to treatment (if able to assess).

   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 **September 6, 2023, inclusive**.

   For patients enrolled in the PSP and receiving the PSP-supplied drug in a private infusion clinic, these patients can be transitioned to the hospital or cancer centre and continue to receive PSP-supplied drug until **September 6, 2023**. The hospital or cancer centre should coordinate the supply of PSP-supplied drug between the PSP and their respective sites, if not done so already.

   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 CADTH recommendations, Ontario Health (Cancer Care Ontario) does not reimburse hospitals for pembrolizumab given as "fixed" or "flat" dose (e.g., 200 mg IV every 3 weeks). Regardless of the patient's prior funding source or prior dosing, the NDFP funded dose is pembrolizumab 2 mg/kg IV given every 3 weeks, up to a maximum of 200 mg per dose (or 4 mg/kg IV given every 6 weeks, up to a maximum of 400 mg per dose), and the funding duration is for a total of 1 years' worth of treatment (17 doses given every 3 weeks, or 9 doses given every 6 weeks).

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:

- Clinic note(s) and/or surgical pathology report to confirm staging.

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

....
Day Month Year