Ontario Health | Santé Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

Pembrolizumab (Adult and Pediatric) - Unresectable or Metastatic MSI-H or dMMR Advanced Solid Tumours

(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

Specify Trial:
○ Clinical Trial 1 ○ Clinical Trial 2
○ Clinical Trial 3 ○ Other

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 patients 6 months or older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumours that have progressed following prior treatment and have no satisfactory alternative treatment options. Patients must also have a good performance status.

☐ Yes

Patients must not have active CNS metastases or a history of therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 drug.

3. Baseline Information

a. ECOG Performance Status at the time of enrolment (for adult patients)
○ 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

c. Please select the primary disease site
○ Breast
○ Central Nervous System
○ Gastrointestinal
○ Genitourinary
○ Gynecological
○ Head and Neck
○ Kaposi's Sarcoma
○ Lung
○ Mesothelioma
○ Ocular
○ Primary Unknown
○ Sarcoma
○ Skin
○ Other (please specify)

d. Is the patient transitioning from a private pay 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	○ 17	○ 18	○ 19	○ 20
○ 21	○ 22	○ 23	○ 24	○ 25	○ 26	○ 27
○ 28	○ 29	○ 30	○ 31	○ 32	○ 33	○ 34

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	○ 9	○ 10	○ 11	○ 12	○ 13
○ 14	○ 15	○ 16	○ 17			

4. Funded Dose

Pembrolizumab 2 mg/kg 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 confirmed disease progression or unacceptable toxicity up 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(s): PEMB]

5. Notes

1. Patients who progress following prior treatment with an anti-PD-1, anti-PD-L1, or anti-PD-L2 drug are not eligible for pembrolizumab funding under this policy.

2. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 year's worth of treatment with pembrolizumab (17 doses given every 3 weeks, or 9 doses given every 6 weeks) 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 the initial course of treatment.

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:
   - A clinic note and imaging (if applicable) from treatment initiation, and
   - The most recent clinic note and imaging (if applicable), and
   - Pathology confirming MSI-H/dMMR status.

   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 August 19, 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 (CDA), 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 2 years for initial treatment, regardless of funding source.

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:
- Pathology report confirming an MSI-H/dMMR solid tumour.
- Clinic notes outlining patient and treatment history/response.
- CT scans demonstrating no disease progression.
- For instances where there is pseudoprogression:
  - Clinic note documenting the assessment and decision to continue, AND
  - 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 1104