Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - Metastatic, Persistent, or Recurrent Carcinoma of the Cervix

(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 for the treatment of adult patients with persistent, recurrent, or metastatic cervical cancer whose tumours express PD-L1 (combined positive score [CPS] ≥ 1) as determined by a validated test, in combination with standard of care chemotherapy, with or without bevacizumab.

☐ Yes

Treatment is only for patients who have not received prior systemic chemotherapy for metastatic or advanced disease, have a good performance status, and whose disease is not amenable to curative treatment.

Patients must also not have active central nervous system (CNS) metastases or significant autoimmune disease.

3. Baseline Information

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

b. Histology
○ Squamous cell carcinoma
○ Adenosquamous carcinoma
○ Adenocarcinoma

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

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

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

f. 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

g. 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 given intravenously (IV) (up to a maximum of 200 mg) every 3 weeks
or
Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks.

Treatment should continue until 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.

Pembrolizumab should be given in combination with platinum-based chemotherapy, with or without bevacizumab, followed by pembrolizumab maintenance.

[ST-QBP regimen code(s): CISPPACL+PEMB, CISPPACL+BEVA+PEMB, CRBPPACL+PEMB, CRBPPACL+BEVA+PEMB for the induction phase, followed by PEMB(MNT), BEVA+PEMB(MNT) for the maintenance phase]

5. Notes

1. At least 1 cycle of chemotherapy must be given concurrently with pembrolizumab (with or without bevacizumab) before changing to pembrolizumab maintenance, with or without bevacizumab.

2. Patients who received cisplatin as part of chemoradiotherapy in the curative setting may still be eligible for pembrolizumab, provided all other eligibility criteria are met.

3. Patients who complete 2 years' worth of treatment without disease progression or recurrence on pembrolizumab may receive up to an additional 1 year's worth of treatment at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Please refer to FAQ viii for additional information.

4. If bevacizumab will be added to the patient's regimen and provided all eligibility criteria are met, please complete a separate enrolment for 'Bevacizumab (Biosimilar) – Metastatic (Stage IVB) Persistent or Recurrent Carcinoma of the Cervix'.

6. FAQs

i. **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 2 years' worth of treatment (35 doses given every 3 weeks, or 18 doses given every 6 weeks).

ii. **My patient is currently on platinum-based doublet chemotherapy without pembrolizumab. Can I add pembrolizumab to the treatment regimen?**

Provided the patient has not progressed on treatment and meets all eligibility criteria, the addition of pembrolizumab to chemotherapy, with or without bevacizumab, may be funded under this policy. Please submit as a prior approval request including a clinic note from the initiation of treatment, and a recent note outlining response to treatment, if able to assess.

iii. **My patient is awaiting their PD-L1 biomarker results. Can we start therapy with chemotherapy, with or without bevacizumab, in the interim?**

As turnaround times for PD-L1 testing may vary, chemotherapy with or without bevacizumab can be initiated first. Once the PD-L1 CPS of greater than or equal to 1 is confirmed, pembrolizumab may be added by submitting as a prior approval, provided they meet all other eligibility criteria for funding under this policy.

iv. **How many chemotherapy cycles should be given concurrently with pembrolizumab?**

Chemotherapy should be continued for up to 6 cycles with pembrolizumab. However, concurrent chemotherapy beyond 6 cycles may be permitted if there is clinical benefit. If chemotherapy cannot be tolerated and is discontinued before 6 cycles, pembrolizumab may be continued with or without bevacizumab.

v. **My patient cannot receive platinum-based chemotherapy. Would my patient be eligible for pembrolizumab with an alternative chemotherapy regimen?**

Provided all other eligibility criteria are met, patients who are unable to receive a platinum agent and/or a taxane may be eligible for pembrolizumab through the NDFP. Sites should submit these requests as a prior approval request in eClaims including a clinic note(s) outlining the patient's treatment history and inability to receive a platinum agent and/or a taxane.

vi. **My patient cannot tolerate the chemotherapy combination. Is pembrolizumab eligible for continued funding?**

Patients who experience intolerance to one or both chemotherapy agents are eligible for continued funding of pembrolizumab (with or without bevacizumab) with the remaining chemotherapy agent or as maintenance.

vii. **My patient had to discontinue bevacizumab due to toxicity. Is pembrolizumab eligible for continued funding?**

Patients who discontinue bevacizumab due to toxicity are eligible for continued funding of pembrolizumab plus chemotherapy or as maintenance.

viii. **My patient completed 2 years of pembrolizumab treatment and experienced disease progression while off pembrolizumab. Is my patient eligible for retreatment?**

Patients who complete 2 years of treatment without disease progression or recurrence may be eligible for up to 1 year's worth of retreatment (i.e., 17 cycles given every 3 weeks, or 9 cycles given every 6 weeks) with pembrolizumab at the point of confirmed disease progression. Pembrolizumab retreatment may be funded as monotherapy, or given in combination with chemotherapy, at the physician's discretion. Claims should be submitted under the same form used for initial treatment.

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) outlining treatment history.
- CT scans every 3 to 6 months indicating no disease progression.
- In instances where there is pseudoprogression, a clinic note(s) documenting the assessment and decision to continue, and the subsequent CT scan confirming no disease progression.
- Pathology report confirming PD-L1 CPS ≥ 1.

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

Day Month Year

Form 1023