

Pembrolizumab - In Combination with Chemoradiotherapy for Locally Advanced Cervical 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 (m²): _____

* 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:

<input type="radio"/> 1-Unknown primary (submit pathology report and clinic note)	<input type="radio"/> 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below)
<input type="radio"/> 3-Regimen modification - schedule (complete questions a and b)	<input type="radio"/> 4-Regimen modification - drug substitutions (complete questions a and c)
<input type="radio"/> 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f)	<input type="radio"/> 6-Maintenance therapy delay (submit clinic note)
<input type="radio"/> 7-Prior systemic therapy clinical trials (complete question g)	<input type="radio"/> 8-Modification due to supply interruption/drug shortage
<input type="radio"/> 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:

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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:

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2. Eligibility Criteria

Pembrolizumab will be used in combination with chemoradiotherapy, followed by pembrolizumab maintenance, for the treatment of Yes adult patients with locally advanced cervical cancer.

Patients must have:

- Stage III-IVA* cervical cancer.
- Squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma of the cervix.
- A good performance status.

*According to the International Federation of Gynecology and Obstetrics (FIGO) staging system 2018.

3. Baseline Information

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

b. Tumour histology Squamous cell carcinoma Adenocarcinoma
 Adenosquamous carcinoma

c. Disease Stage IIIA IIIB IIIC1 IIIC2 IVA

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, how many doses of every 3 week pembrolizumab did the patient receive prior to the transition? 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 every 6 week pembrolizumab did the patient receive prior to the transition? 1 2 3 4 5 6 7 8
 9 10 11 12 13 14 15

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

4. Funded Dose

Cycles 1 to 5:

Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 3 weeks with concurrent chemoradiotherapy.

Cycle 6 and onward:

Pembrolizumab 2 mg/kg given 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.

Treatment should continue until disease progression or unacceptable toxicity, up to a maximum of 2 years (approximately 105 weeks), whichever comes first.

[ST-QBP regimen code(s): CISP(RT-W)+PEMB, CRBP(RT)+PEMB, PEMB]

5. Notes

1. One additional cycle of pembrolizumab (i.e., cycle 6) may be given with concurrent chemoradiotherapy, to facilitate chemoradiotherapy treatment logistics.
2. Patients whose disease recurs at least 6 months after the last dose of pembrolizumab may be funded for 1 line of immune checkpoint inhibitor therapy for metastatic, persistent, or recurrent cervical cancer.

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).

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 April 20, 2026, 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, the 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 (105 weeks), regardless of funding source.

3. My patient is experiencing intolerable toxicity to the chemotherapy portion. Can they continue pembrolizumab with radiotherapy?

The chemotherapy portion may be stopped if the patient has intolerable toxicity, and pembrolizumab with radiotherapy may be continued.

4. My patient received sequential chemotherapy and radiation. Can pembrolizumab be started after?

Pembrolizumab is only funded for patients who receive concurrent chemoradiotherapy.

5. My patient recently completed chemoradiotherapy. Can pembrolizumab be started after?

No, patients must receive chemoradiotherapy concurrently with the initiation of pembrolizumab.

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 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):

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Day Month Year

Form 1129