Ontario Health | Santé Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

Pembrolizumab - Primary Advanced or Recurrent Endometrial Carcinoma

(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 in combination with carboplatin and paclitaxel for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma. ☐ Yes

Patients must have:

- Newly diagnosed stage III or IVA with measurable disease; or stage IVB or recurrent endometrial cancer, with or without measurable disease; AND
- A good performance status.

Patients must not:

- Have experienced their first disease recurrence within 6 months of completing (neo)adjuvant systemic anticancer therapy; OR
- Been previously treated with an immune checkpoint inhibitor; OR
- Have uncontrolled brain metastases; OR
- Have carcinosarcoma.

3. Baseline Information

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

b. Disease setting ○ Newly diagnosed ○ Recurrent

c. Disease stage ○ Stage III ○ Stage IVA ○ Stage IVB

d. MMR/ MSI status ○ dMMR/MSI-H ○ pMMR/MSI-L or MSS ○ Unknown

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

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	○ 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 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 or equivalent (35 doses of every 3-week dosing, or 18 doses of every 6-week dosing), whichever comes first.

Pembrolizumab should be given in combination with carboplatin and paclitaxel for the first 6 cycles, followed by maintenance.

[ST-QBP regimen code(s): CRBPPACL+PEMB, CISPPACL+PEMB, PEMB(MNT)]

5. Notes

1. At least one cycle of platinum-based chemotherapy must be given with pembrolizumab.

2. Cisplatin may be substituted for carboplatin.

3. Patients who complete 2 years' worth of treatment without disease progression may receive up to 1 additional 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 and provided that no other systemic treatment is given in between. 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).

   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 December 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, 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.

3. **My patient is receiving carboplatin, paclitaxel, and pembrolizumab but cannot tolerate the chemotherapy portion. Going forward, will pembrolizumab be funded if given as a monotherapy?**

   For patients who have initiated treatment and cannot tolerate the chemotherapy portion, pembrolizumab will be funded as monotherapy.

4. **My patient is currently receiving a platinum and paclitaxel. Can I add pembrolizumab to the chemotherapy backbone?**

   Provided the patient has not progressed on treatment and meets all the eligibility criteria, the addition of pembrolizumab may be funded under this policy. Please submit as a prior approval request in eClaims including the most recent clinic note outlining the treatment history and response to treatment, if able to assess.

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): .....

....
Day Month Year

Form 1115