Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - In Combination with Lenvatinib for Advanced Endometrial 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 (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 lenvatinib) for previously treated advanced, recurrent, or metastatic endometrial cancer patients who are not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR). ☐ Yes

Eligible patients must have:

- Disease progression following platinum-based systemic therapy AND
- A good performance status.

Patients must not:

- Be a candidate for curative surgery or radiation OR
- Have unstable central nervous system metastases.

3. Baseline Information

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

b. Is the patient transitioning from a private pay or compassionate program? ○ Yes ○ No

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

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

e. 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

f. 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, or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks.

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): LENV+PEMB, LENV(MNT)]

5. Notes

1. Completion of this form is for pembrolizumab funding only. Funding for lenvatinib must be obtained through the Ministry's Exceptional Access Program. Please check that your patient will be eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration into the Trillium Drug Program.

2. Patients who have received more than 1 prior line of platinum-based chemotherapy will be eligible for NDFP funding provided all other eligibility criteria are met.

3. Patients with treated or stable CNS metastases and/or autoimmune disease may be eligible for treatment at the discretion of the treating physician.

4. Patients with carcinosarcoma (also referred to as malignant mixed Müllerian tumor) will be eligible for funding provided all other eligibility criteria are met. Conversely, patients with sarcoma (e.g., endometrial leiomyosarcoma, endometrial stromal sarcoma) will not be eligible for funding.

5. Lenvatinib may be continued after pembrolizumab treatment has been completed.

6. 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 (either given with or without lenvatinib), at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment.

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 through the NDFP.

2. **What is the process for transitioning my patient from a non-publicly funded program for pembrolizumab 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 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 November 9, 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 November 9, 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 recommendations from the Canadian Agency for Drugs and Technologies in Health (CADTH), 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.

3. **One of the components of this regimen is discontinued due to toxicity, will NDFP continue to provide funding for the remaining medication?**

   If pembrolizumab or lenvatinib requires discontinuation, funding will continue for the remaining component of the regimen until disease progression or unacceptable toxicity (up to a maximum of 2 years for pembrolizumab).

4. **My patient is awaiting their MSI-MMR results. Can they start therapy with pembrolizumab in combination with lenvatinib in the interim?**

   No, MSI or MMR status must be determined before initiating treatment with pembrolizumab in combination with lenvatinib to ensure patients do not have MSI-H or dMMR disease.

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 microsatellite stable (MSS) disease or proficient MMR status.
- Clinic notes outlining patient and treatment history/response.
- 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.

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

....
Day Month Year

Form 1033