Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - Previously Treated MSI-H/dMMR 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 is used as monotherapy for the treatment of adult patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) endometrial carcinoma whose tumours have progressed following prior chemotherapy. ☐ Yes

Treatment is only for patients who have not received prior therapy with a programmed cell death 1 protein (PD-1) or programmed cell death ligand 1 (PD-L1) inhibitor, do not have active central nervous system (CNS) metastases or active autoimmune disease, and who have a good performance status.

3. Baseline Information

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

b. Is the patient transitioning from a private payer 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 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.

[ST-QBP regimen code(s): PEMB]

5. Notes

1. 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.

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 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 **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 the recommendations from 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. **My patient is awaiting their MSI/MMR results. Can we start therapy with pembrolizumab in the interim?**

   No, MSI-H/dMMR status must be determined before initiating NDFP-funded pembrolizumab.

4. **My patient has an endometrial carcinosarcoma. Are they eligible for pembrolizumab?**

   Provided all other eligibility criteria are met, patients with endometrial carcinosarcomas may be eligible for NDFP-funded pembrolizumab. Conversely, patients with pure endometrial sarcomas are not eligible for funding.

5. **My patient cannot tolerate their current chemotherapy regimen. Can my patient switch to pembrolizumab?**

   Patients who experience intolerance to their chemotherapy regimen may be eligible to switch to pembrolizumab monotherapy, provided all other eligibility criteria are met.

6. **My patient is being treated in a subsequent line after receiving platinum-based chemotherapy. Are they eligible to switch to pembrolizumab?**

   Provided all eligibility criteria are met, on a time-limited basis, patients may be eligible to switch to pembrolizumab. The decision to change therapy should be at the discretion of the treating physician. 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. Patients who are responding to their current therapy will be able to access pembrolizumab in a subsequent line of therapy.

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 MSI-H/dMMR status.

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

18 07 2023
Day Month Year

Form 1029