Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - Previously Treated Locally Advanced or Metastatic Urothelial Carcinoma

(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
- ○ 9-Supplemental doses requested
- ○ 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

The patient must meet the following criteria:

- Pembrolizumab is used for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (MUC) who have disease progression during or following platinum-containing chemotherapy or within 12 months of completing neoadjuvant or adjuvant platinum-containing chemotherapy. ☐ Yes

  Treatment should be for patients with good performance status.

3. Baseline Information

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

b. Disease stage
- ○ Locally advanced
- ○ Metastatic

c. Previous treatment received
- ☐ Neoadjuvant platinum-containing chemotherapy
- ☐ Adjuvant platinum-containing chemotherapy
- ☐ Platinum-containing chemotherapy for locally advanced or metastatic disease
- ☐ Other (Prior Approval required)

Specify: .....

d. Is the patient transitioning from a private pay/compassionate program? ○ Yes ○ No

e. If yes, how many cycles did the patient have 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		

4. Funded Dose

Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or
Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days.

Treatment should continue until confirmed disease progression or unacceptable toxicity 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: PEMB]

5. Notes

1. Ontario Health (Cancer Care Ontario) will fund one line of immunotherapy for locally advanced or metastatic urothelial carcinoma.
2. Patients who complete 2 years' worth of treatment without disease progression 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. Claims should be submitted under the same enrolment form used for initial treatment.
3. Patients who meet criteria are eligible for one line of avelumab or pembrolizumab for advanced urothelial carcinoma (unresectable, locally advanced or metastatic).
4. Pembrolizumab funding is for single agent use only.

6. FAQs

i. **My patient is currently receiving pembrolizumab through private means. Can my patient be transitioned over to receive funding through the New Drug Funding Program (NDFP)?**

Provided the funding 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 New Drug Funding Program.

At the NDFP funded dose of 2 mg/kg (up to a maximum of 200 mg per dose) or 4 mg/kg (up to a maximum of 400 mg per dose), funding is for a total of 2 years' worth of treatment (or equivalent) for the initial course, regardless of the funding source.

ii. **My patient has been treated with two or more lines of chemotherapy and is still fit for further treatment. Would my patient be eligible for pembrolizumab?**

Patients treated with two or more lines of therapy with at least one line of platinum-based chemotherapy may be eligible for pembrolizumab, provided all other eligibility criteria are met.

iii. **My patient could not receive platinum-based chemotherapy and was previously treated with an alternative chemotherapy regimen. Would my patient be eligible for pembrolizumab?**

Provided all other eligibility criteria are met, patients with contraindications for platinum and who have received an alternative chemotherapy may be eligible for pembrolizumab through the New Drug Funding Program. Sites should submit these requests as a Prior Approval in eClaims (along with the most recent clinic note).

iv. **My patient is currently receiving pembrolizumab on an every 3 week schedule. Can my patient be transitioned over to an every 6 week schedule?**

The decision to switch should be based on a discussion between the clinician and patient. Switches between schedules (from every 3 weeks to every 6 weeks or vice versa) will be eligible for continued funding provided the patient's disease has not progressed. Please note that the funded duration remains the same (i.e., a maximum of two years for the initial treatment course plus one additional year of retreatment, if eligible).

7. Supporting Documents

None required.

In the event of an audit, the following should be available to document eligibility:

- CT scans every 3 to 6 months, along with clinic notes indicating no disease progression
- In instances where there is pseudoprogression, a clinic note 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