Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - In Combination with Lenvatinib for First-Line Advanced or Metastatic Renal Cell 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 is used in combination with lenvatinib for the treatment of adult patients with advanced or metastatic renal cell carcinoma (RCC) who have not received prior systemic therapy for advanced disease. ☐ Yes

Treatment is only for patients whose disease is not amenable to curative surgery or radiation, and who have a good performance status.

3. Baseline Information

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

b. Histology ○ Clear cell ○ Non-clear cell

c. Patient's IMDC risk stratification ○ Favourable ○ Intermediate ○ Poor

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

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

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

g. 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

h. 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): 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 with treated or stable CNS metastases and/or autoimmune disease may be eligible for treatment, at the discretion of the treating physician.

3. Patients who have a disease-free interval of 6 months or greater after completion of adjuvant therapy may be eligible for one line of immune checkpoint inhibitor-based therapy for advanced or metastatic renal cell carcinoma provided all other eligibility criteria are met.

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

5. 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 with lenvatinib 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).

   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. **My patient has non-clear cell RCC. Are they eligible for pembrolizumab?**

   Provided all other eligibility criteria are met, patients with non-clear cell histology are eligible.

4. **My patient is intolerant to pembrolizumab or lenvatinib. Can I continue therapy with the other agent?**

   Patients who are intolerant to either pembrolizumab or lenvatinib may continue therapy with the other agent until disease progression or unacceptable toxicity (up to a maximum of 2 years for pembrolizumab).

5. **My patient cannot tolerate their alternate first-line regimen. Can my patient switch to pembrolizumab with lenvatinib?**

   Patients who experience intolerance to an alternate first-line regimen may be eligible to switch to pembrolizumab with lenvatinib, provided all other eligibility criteria are met and no disease progression has occurred.

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.

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

Day Month Year

Form 1032