Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - In Combination with Axitinib for First Line Advanced or Metastatic Renal Cell 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 in combination with axitinib for the first line treatment of patients with advanced or metastatic renal cell carcinoma (RCC) who have good performance status. ☐ Yes

3. Baseline Information

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

b. Please select the patient's risk stratification: ○ Favourable ○ Intermediate ○ Poor

c. Tumour histologic type: ○ Clear cell ○ Non-clear cell

d. Does the patient have stable brain metastases? ○ Yes ○ Not applicable, the patient does not have brain metastases

e. Is the patient transitioning from a private payer or compassionate program? ○ Yes ○ No

d. If yes, how many cycles did the patient have prior to transitioning to public funding?

○ 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. Axitinib should be continued until disease progression or unacceptable toxicity.

[ST-QBP regimen code: AXIT+PEMB for combination therapy, AXIT(MNT) for axitinib maintenance portion]

5. Notes

1. Please refer to the Ontario Drug Benefit Exceptional Access Program for full funding criteria for axitinib.

2. 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.

3. For patients who stop pembrolizumab without disease progression, continuation of pembrolizumab (to complete 2 years' worth of treatment) will be funded provided that no other treatment is given in between.

4. Patients who complete 35 cycles without disease progression may receive up to an additional 17 cycles of pembrolizumab monotherapy at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same form used for initial treatment.

6. FAQs

i. **My patient is currently receiving pembrolizumab (in combination with axitinib) through non-publicly funded 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 NDFP. Please submit as a prior approval request including the most recent clinic note (outlining the response to pembrolizumab and axitinib, if able to assess).

Please note that the NDFP funded dose is 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), and the funding is for a total of 2 years' worth of treatment for the initial course (35 treatments), regardless of the funding source.

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

Patients who are intolerant to either pembrolizumab or axitinib may continue therapy with the other agent until disease progression or unacceptable toxicity (up to a maximum of 35 cycles for pembrolizumab or until progressive disease for axitinib).

iii. **My patient is currently on an alternate 1st line therapy (e.g. sunitinib, pazopanib) and can no longer tolerate therapy. Can I switch my patient to pembrolizumab with axitinib?**

Patients who started alternate first line therapies may switch once to pembrolizumab with axitinib in the event of toxicity that occurs within 3 months of starting the other first line therapy. Similarly, patients who initiate therapy with pembrolizumab with axitinib may switch to another first line treatment regimen in the first 3 months of starting treatment, provided the funding criteria for the alternate first line therapy are met.

iv. **What publicly funded treatments are available after disease progression on pembrolizumab in combination with axitinib?**

Patients may be eligible for second line cabozantinib after disease progression on pembrolizumab in combination with axitinib. Please refer to the Ministry's Exceptional Access Program for details.

v. **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 at the time of enrolment.

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

Form 1006