Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - Adjuvant Treatment for 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 for the adjuvant treatment of adult patients* with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence post-nephrectomy, or following nephrectomy and resection of metastatic lesions. ☐ Yes

Treatment is only for patients who have not received previous systemic treatment for advanced RCC and have good performance status.

Treatment with pembrolizumab should be initiated within 12 weeks of complete resection.

*Eligible patients include those who have:

- Histologically confirmed RCC with a clear cell component, with or without sarcomatoid features;
- Intermediate-high or high-risk recurrence post-nephrectomy, or M1 with no evidence of disease (M1 NED) following nephrectomy and metastasectomy; and
- Partial or radical nephrectomy (and complete metastasectomy in M1 NED patients) with negative surgical margins 4 weeks or more before the initiation of treatment.

3. Baseline Information

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

b. Disease risk of recurrence classification ○ M0, intermediate-to-high risk ○ M0, high risk ○ M1 NED

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

d. If yes, how many doses of pembrolizumab given every 3 weeks did the patient receive prior to transition?

○ N/A ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8
○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ 15 ○ 16

e. If yes, how many doses of pembrolizumab given every 6 weeks did the patient receive prior to transition?

○ N/A ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8

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 recurrence, or unacceptable toxicity, up to a maximum of 12 months (or equivalent therapy*), whichever comes first.

*17 cycles if administered every 3 weeks, or 9 cycles administered every 6 weeks.

[ST-QBP regimen code: PEMB]

5. Notes

1. Pembrolizumab is funded for single agent use only.

2. Intermediate-high risk RCC is defined as:
    - pT2, grade 4 or sarcomatoid, N0, M0
    - pT3, any grade, N0, M0

3. High risk RCC is defined as:
    - pT4, any grade, N0, M0
    - pT any stage, any grade, N+, M0

4. M1 NED is defined as a primary tumour and solid, isolated, soft-tissue metastases that could be completely resected at the time of nephrectomy (synchronous) or 1 year or less from date of nephrectomy (metachronous).

5. Patients who progress while on or within 6 months of adjuvant pembrolizumab are not eligible for immune checkpoint inhibitor-based therapy for advanced or metastatic RCC.

6. Patients with a histology other than clear cell are not eligible for funding under this policy.

6. FAQs

i. **My patient is currently receiving pembrolizumab through non-publicly funded means as adjuvant therapy for RCC. Can my patient be transitioned over to receive funding 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 pembrolizumab funding through NDFP. Please submit as a prior approval request including a clinic note(s) and, if applicable, imaging (a) from initiation of treatment and (b) documenting the response to treatment (if able to assess).

Of note, patients enrolled in the manufacturer's Patient Support Program (PSP) will continue to receive treatment through the PSP until June 14, 2023, inclusive. While these patients may enroll before June 15, 2023, please be aware any treatments submitted to eClaims that were given on or before June 14, 2023 will be denied.

Based on CADTH recommendations, Ontario Health (Cancer Care Ontario) does not reimburse hospitals for pembrolizumab given as a "fixed" or "flat" dose (e.g., 200 mg IV every 3 weeks). Regardless of the patient's prior funding source or prior dosing, the NDFP funded dose is pembrolizumab 2 mg/kg IV given every 21 days, up to a maximum of 200 mg per dose (or 4 mg/kg given every 42 days, up to a maximum of 400 mg per dose), and the funding duration is for the equivalent of 12 months maximum, regardless of funding source. Please refer to the 'funded dose' section of this policy.

ii. **What treatment options are available for patients who relapsed while on adjuvant pembrolizumab?**

Patients who relapse on or within 6 months of adjuvant pembrolizumab may be eligible for tyrosine kinase inhibitors (TKIs) (e.g., sunitinib, cabozantinib, pazopanib, or axitinib). Please refer to the Ministry of Health's Exceptional Access Program for the full reimbursement criteria for specific TKIs.

iii. **My patient has completed their full course of adjuvant pembrolizumab, but their disease has now recurred. Is my patient eligible for funding of immune checkpoint inhibitor-based therapy?**

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 RCC provided all other eligibility criteria are met.

iv. **My patient needs to take a treatment break from pembrolizumab. Will resumption of treatment be funded?**

For patients who stop pembrolizumab without disease progression, continuation of pembrolizumab (to complete the equivalent of 12 months of adjuvant treatment, regardless of the time interval) will be funded provided that no other treatment is given in between.

Supporting Documents

None required at the time of enrolment.

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

- Clinic note(s) indicating no prior systemic therapy for advanced RCC.
- Pathology report demonstrating histologically confirmed RCC with a clear cell component, with or without sarcomatoid features.
- Clinic note(s) and/or surgical pathology report(s) showing partial or radical nephrectomy and complete metastasectomy in M1 NED patients with negative surgical margins.

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

....
Day Month Year

Form 1005