Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - First-line Treatment of Advanced Esophageal and Esophagogastric Junction 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

The patient must meet the following criteria:

Pembrolizumab is used in combination with platinum and fluoropyrimidine-based chemotherapy for the first-line treatment of locally advanced unresectable or metastatic esophageal adenocarcinoma or squamous cell carcinoma, or human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic adenocarcinoma of the esophagogastric junction (EGJ) in patients with good performance status.

☐ Yes

3. Baseline Information

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

b. The patient has locally advanced unresectable or metastatic _____
○ Esophageal adenocarcinoma
○ Esophageal squamous cell carcinoma
○ HER2-negative adenocarcinoma of the EGJ

c. The patient has stable brain metastases
○ Yes
○ Not applicable: the patient does not have brain metastases

d. HER2 test results
○ HER2-positive ○ HER2-negative
○ Test result not yet available
○ Not applicable based on histology

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

f. If yes to 3e, was the patient on an every 3 week dosing schedule of pembrolizumab?
○ Yes ○ No

g. If yes to 3f, how many treatments of every 3 week pembrolizumab 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		

h. If no to 3f, how many treatments of every 6 week pembrolizumab 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	

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.

When used as combination therapy, pembrolizumab must be given with a fluoropyrimidine and a platinum for up to 6 cycles, followed by pembrolizumab maintenance.

[ST-QBP regimen codes: CISPFU+PEMB, CRBPFU+PEMB, CAPECISP+PEMB, CAPECRBP+PEMB, MFOLFOX6+PEMB, or XELOX+PEMB for the induction phase, followed by PEMB(MNT) for the maintenance phase].

5. Notes

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

2. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 years' worth of treatment with pembrolizumab, with or without chemotherapy, at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment and provided that no other systemic treatment is given in between. Claims should be submitted under the same form used for the initial course of treatment.

3. At least 1 cycle of chemotherapy must be given concurrently with pembrolizumab before changing to pembrolizumab maintenance due to intolerance.

4. Patients who received prior adjuvant therapy with an immune checkpoint inhibitor may be eligible for pembrolizumab in combination with chemotherapy in the advanced setting provided there was a disease-free interval (DFI) of 6 months or greater after completing adjuvant therapy.

6. FAQs

i. **My patient is currently receiving pembrolizumab for esophageal or EGJ carcinoma through non-publicly funded means. Can my patient be transitioned over to receive funding under 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 of pembrolizumab through the NDFP. Please submit as a prior approval request in eClaims including the most recent clinic note (outlining the response to treatment, if able to assess) and the number of pembrolizumab treatments received to date.

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 3 weeks, up to a maximum of 200 mg per dose (or 4 mg/kg given every 6 weeks, up to a maximum of 400 mg per dose), and the funding duration is for a total of 2 years' worth of treatment for the initial course (35 doses given every 3 weeks, or 18 doses given every 6 weeks), regardless of funding source.

ii. **My patient already initiated first-line chemotherapy with a platinum and a fluoropyrimidine. Can I add pembrolizumab?**

Provided the patient has not progressed on treatment, and meets all the eligibility criteria, the addition of pembrolizumab may be funded under this policy. Please submit as a prior approval request in eClaims including the most recent clinic note outlining the treatment history and response to treatment, if able to assess.

iii. **My patient is awaiting human epidermal growth factor receptor 2 (HER2) test results. Can we start therapy with pembrolizumab and chemotherapy in the interim?**

Patients may initiate therapy with a platinum and fluoropyrimidine-based chemotherapy regimen while awaiting HER2 test results. Once HER2-negative status is confirmed, pembrolizumab may be added by submitting as a prior approval provided they meet all other eligibility criteria for funding under this policy.

iv. **My patient has progressed after receiving pembrolizumab for advanced adenocarcinoma of the EGJ. What can my patient receive as a subsequent line of therapy?**

Patients who receive pembrolizumab under this policy may be eligible to receive other therapies currently funded by the NDFP (e.g., ramucirumab) and/or the Ministry's Exceptional Access Program (EAP) (e.g., trifluridine-tipiracil) for EGJ adenocarcinoma provided all funding criteria are met under the selected policy. Please refer to the respective NDFP and EAP policies for more 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).

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 notes documenting treatment history.
- 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.
- Pathology report demonstrating HER2-negativity.

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

....
Day Month Year

Form 962