Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

# Pembrolizumab - First-line Treatment of Advanced HER2-negative Esophageal, Gastric, and Esophagogastric Junction Carcinoma

This is a renamed version of 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

Pembrolizumab is used in combination with platinum and fluoropyrimidine-based chemotherapy for the first-line treatment of adult patients with locally advanced unresectable or metastatic, human epidermal growth factor receptor 2 (HER2)-negative, esophageal adenocarcinoma or squamous cell carcinoma, gastric adenocarcinoma, or esophagogastric junction (EGJ) adenocarcinoma. Patients must have a good performance status and must not have active uncontrolled CNS metastases.

☐ Yes

## 3. Baseline Information

a. ECOG status at time of enrolment
○ 0 ○ 1 ○ 2

b. The patient has locally advanced unresectable or metastatic _____
○ Esophageal adenocarcinoma
○ Esophageal squamous cell carcinoma
○ EGJ adenocarcinoma
○ Gastric adenocarcinoma
○ Gastric squamous cell or undifferentiated carcinoma

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

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 to 3d, 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 (with or without a fluoropyrimidine).

[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 (i.e.: 17 doses if given every 3 weeks or 9 cycles if given every 6 weeks), 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.

5. Patients with a history of anti-PD-1, anti-PD-L1, or anti-PD-L2 therapy, in the advanced or metastatic setting will be ineligible.

6. Patients with squamous cell or undifferentiated gastric cancer are eligible for funding under this policy.

## 6. FAQs

1. **My patient is currently receiving pembrolizumab for esophageal, gastric, 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 through the NDFP.

   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).

   **Please note:** Patients with gastric or EGJ carcinoma who meet the NDFP eligibility criteria and are enrolled in the manufacturer's patient support program (PSP) are eligible to receive continued drug supply through the PSP until May 12, 2025, inclusive. After this date, patients who met the NDFP eligibility criteria at the point of treatment initiation are eligible to transition to NDFP funding for the remainder of their treatment course. Although sites may enroll their patient onto this policy at any time beforehand, any treatment claims submitted to eClaims that were given on or before the PSP transition date will be denied.

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

2. **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.

## 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 1083*