Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab and Trastuzumab (Biosimilar) - First-line Treatment of Advanced HER2-Positive Gastric or Esophagogastric Junction Adenocarcinoma

(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 and trastuzumab are used in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adult patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive gastric or esophagogastric junction (EGJ) adenocarcinoma.

☐ Yes

Patients must have:

- PD-L1 combined positive score (CPS) ≥ 1; AND,
- HER2-positive disease by a validated test (immunohistochemistry (IHC) 3+, or IHC 2+ with amplification by fluorescence in situ hybridization (FISH)); AND,
- A good performance status.

Patients must not have:

- Active central nervous system (CNS) metastases; NOR,
- History of therapy with an anti-programmed cell death protein 1 (PD-1), or anti-programmed cell death-ligand 1 or 2 (PD-L1 or PD-L2), drug in the advanced or metastatic setting.

3. Baseline Information

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

b. The patient has locally advanced unresectable or metastatic _____
○ Gastric Adenocarcinoma
○ EGJ Adenocarcinoma
○ Esophageal Adenocarcinoma

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 to 3d, 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?

○ 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 no to 3f, how many treatments of every 6-week pembrolizumab did the patient have prior to transitioning to public funding?

○ N/A	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
○ 7	○ 8	○ 9	○ 10	○ 11	○ 12	○ 13
○ 14	○ 15	○ 16	○ 17			

i. If yes to 3d, please indicate the date of the last administered dose

Day _____ Month _____ Year _____

4. Funded Dose

Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 3 weeks, or 4 mg/kg given IV (up to a maximum of 400 mg) every 6 weeks.

Trastuzumab 8 mg/kg loading dose given IV on day 1 of cycle 1, then 6 mg/kg given IV every 3 weeks, or 6 mg/kg loading dose given IV on day 1 of cycle 1, then 4 mg/kg IV every 2 weeks.

Treatment with pembrolizumab and trastuzumab should continue until disease progression or unacceptable toxicity, up to a maximum of 2 years of pembrolizumab (or equivalent; 35 doses of every 3-week dosing, or 17 doses of every 6-week dosing), whichever comes first. Patients who complete 2 years'-worth of pembrolizumab may continue trastuzumab (with capecitabine or fluorouracil) for one additional year.

[ST-QBP regimen code(s): MFOLFOX6+PEMB+TRAS, CISPFU+PEMB+TRAS, CRBPFU+PEMB+TRAS, CAPECISP+PEMB+TRAS, CAPECRBP+PEMB+TRAS, XELOX+PEMB+TRAS; then FU+PEMB+TRAS, CAPE+PEMB+TRAS, PEMB+TRAS(MNT), TRAS(MNT) for maintenance therapy]

5. Notes

1. Completion of this form will enroll the patient for both pembrolizumab and trastuzumab (biosimilar) funding.

2. At least 1 cycle of chemotherapy must be given concurrently with pembrolizumab and trastuzumab.

3. Patients with HER2-positive esophageal adenocarcinoma are eligible for funding under this policy.

4. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 year's worth of treatment with pembrolizumab (17 doses given every 3 weeks, or 9 doses given every 6 weeks) with or without trastuzumab and/or 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.

5. Patients who received prior adjuvant therapy with an immune checkpoint inhibitor may be eligible for pembrolizumab and trastuzumab (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

1. **My patient is currently receiving pembrolizumab through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned 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 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).

   Please note: Patients 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 February 15, 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.

   Based on the recommendations from Canada's Drug Agency (CDA), 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.

   The NDFP will fund a total duration of 2 years of pembrolizumab, regardless of funding source.

3. **My patient is awaiting HER2 and/or PD-L1 test results. Can we start therapy with pembrolizumab and trastuzumab (with chemotherapy) in the interim?**

   Patients may initiate chemotherapy while awaiting test results. Once PD-L1 CPS = 1 and HER2 positivity are confirmed, pembrolizumab and trastuzumab may be added.

4. **My patient is currently receiving trastuzumab with chemotherapy. Can pembrolizumab be added?**

   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.

5. **My patient is intolerant to one of the drugs in the regimen. Can we continue therapy with the remaining agent(s)?**

   Patients who are intolerant to one or more components of the regimen may continue therapy with the remaining agent(s) until disease progression, unacceptable toxicity, or until the maximum funded duration, whichever comes first.

6. **My patient is currently on maintenance trastuzumab. Can pembrolizumab be added?**

   No, only patients who are currently receiving platinum plus fluoropyrimidine-based chemotherapy with trastuzumab may add pembrolizumab.

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:

- Pathology report(s) and biomarker test results.
- Clinic notes outlining patient and treatment history/response.
- CT scans demonstrating no disease progression while on treatment.

For instances where there is pseudoprogression:

- Clinic note documenting the assessment and decision to continue, AND
- Confirmatory scan conducted preferably at 6 to 8 weeks but no later than 12 weeks after the initial disease progression to confirm the absence of true progression.

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

Day Month Year

Form 1078