Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Trastuzumab (Biosimilar) - Advanced Gastric, Gastroesophageal, or Esophageal Cancer

(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 (comple 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:

a. Trastuzumab will be used in combination with intravenous 5-fluorouracil (or capecitabine) and cisplatin or with an oxaliplatin-based regimen for the treatment of patients with HER2-positive advanced (non-resectable; either locally advanced, recurrent, or metastatic) adenocarcinoma of the esophagus, stomach or gastroesophageal junction who have not received prior systemic therapy treatment for their metastatic disease ☐ Yes

b. Trastuzumab should only be administered to patients with advanced esophageal, gastroesophageal junction or gastric cancer (non-resectable; either locally advanced, recurrent, or metastatic) whose tumours have HER2 overexpression (by IHC2+ [and confirmed by FISH+], or IHC3+, as determined by an accurate and validated assay) ☐ Yes

3. Funded Dose

Trastuzumab loading dose of 8mg/kg IV on Day 1 of the first cycle, followed by 6 mg/kg every 3 weeks until disease progression or unacceptable toxicity.

Alternative dosing schedule for FOLFOX: trastuzumab 6 mg/kg IV on Day 1 of the first cycle, followed by 4 mg/kg every 2 weeks until disease progression or unacceptable toxicity.

[ST-QBP regimen codes: CAPECISP+TRAS, CISPFU+TRAS, MFOLFOX6+TRAS, XELOX+TRAS for the chemotherapy plus trastuzumab portion followed by TRAS as monotherapy]

Please select the dosing schedule for trastuzumab:

- ○ Every 3 weeks: Loading dose of 8 mg/kg IV, followed by 6 mg/kg IV
- ○ Every 2 weeks: Loading dose of 6 mg/kg IV, followed by 4 mg/kg IV

4. Notes

1. Chemotherapy may be started and trastuzumab added later provided that there has been no disease progression.
2. Trastuzumab may be continued as a single agent until disease progression following six cycles of trastuzumab-chemotherapy.
3. The patient must have a normal cardiac ejection fraction. Trastuzumab should not be given concurrently with an anthracycline.

5. FAQs

i. **My patient is currently receiving trastuzumab (Herceptin). Can my patient stay on the reference biologic (i.e., trastuzumab (Herceptin))?**

Yes, patients currently on trastuzumab (Herceptin) or initiated on trastuzumab (Herceptin) before December 15, 2019 may continue with the reference biologic until their treatment course has ended.

Patients who are continuing treatment with trastuzumab (Herceptin) after December 15, 2019 must have an enrolment form and treatment claim(s) submitted in eClaims prior to December 15, 2019 to be eligible for continued reimbursement of trastuzumab (Herceptin).

ii. **My patient is currently receiving trastuzumab (Herceptin). Can my patient be switched to a trastuzumab biosimilar for the remainder of their treatment cycles?**

At the discretion of the treating physician or based on individual hospital policy, patients currently on trastuzumab (Herceptin) may be switched over to a trastuzumab (biosimilar) for the remainder of the funded doses if a trastuzumab biosimilar is funded for the specific indication.

If the patient is already enrolled in an NDFP policy for trastuzumab, please re-enroll the patient in the updated trastuzumab enrolment form in order to submit treatments for trastuzumab biosimilars.

iii. **Will the reimbursement rate be the same for all trastuzumab biosimilars?**

Reimbursement prices for trastuzumab biosimilars are located on our price lists which can be accessed via the eClaims Resource Library.

Any incentives or promotions accepted by hospitals related to purchase and/or selection decisions of trastuzumab will be interpreted as lowering the local acquisition cost of trastuzumab, and, consistent with other NDFP policies, are subject to recovery.

6. 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:

- A copy of the pathology report demonstrating HER2 overexpression (by IHC2+ [and confirmed by FISH+], or IHC3+). The report must state clearly the hospital, date of biopsy and the hospital pathology specimen of the original material used for the test.

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

....
Day Month Year