Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

# Trastuzumab (Biosimilar) in combination with Chemotherapy - Metastatic Breast Cancer

(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)

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**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:

## Eligibility Criteria

a. HER2/neu status ☐ Yes

The patient has tested positive for Her2/neu as per Ontario Health (Cancer Care Ontario) criteria:

- IHC 3+
- FISH/SISH ratio ≥ 2

b. Patient has metastatic breast cancer and will be treated with trastuzumab in combination with docetaxel/paclitaxel/vinorelbine.

## 3. Baseline Information

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

* b. Please indicate the chemotherapy to be used with trastuzumab ○ Docetaxel ○ Paclitaxel ○ Vinorelbine

## 4. Funded Dose

Trastuzumab 8 mg/kg as a loading dose intravenously (IV) on day 1 of the first cycle, followed by 6 mg/kg IV every 21 days until disease progression or unacceptable toxicity, whichever comes first.

Treatment should continue until disease progression or unacceptable toxicity.

[ST-QBP regimen code(s):DOCE+TRAS,PACL(W)+TRAS,VINO+TRAS]

## 5. Notes

1. Reimbursement will be discontinued for patients whose disease progresses while being treated with trastuzumab in the metastatic setting.

## 6. FAQs

1. **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).

2. **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.

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

   Reimbursement in eClaims will be adjudicated based on the Drug Identification Number (DIN) submitted, and may be unique to each trastuzumab biosimilar.

   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.

## 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 demonstrating HER2/neu positivity as per Ontario Health (Cancer Care Ontario) criteria.
- Clinic notes outlining patient and treatment history/response.
- CT scans indicating no disease progression.

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

Day Month Year