Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Trastuzumab (Biosimilar) - Adjuvant Treatment for Breast Cancer

This form has been renamed from its old title *Trastuzumab (Biosimilar) - Adjuvant Treatment for HER2/neu-Overexpressing Primary Breast 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

Patient must meet all criteria.

a. The patient has tested positive for Her2/neu as per CCO criteria:

IHC 3+ ☐ Yes

FISH/SISH ≥2 ☐ Yes

b. The patient has:
- ○ Node-positive disease
- ○ Node-negative tumor (with size greater than 1 cm)
- ○ Node-negative tumor (with size less than or equal to 1 cm)

c. The patient has received:
- ○ adjuvant chemotherapy
- ○ neoadjuvant chemotherapy

d. If the patient has received adjuvant/neoadjuvant chemotherapy not funded by NDFP, indicate the chemotherapy regimen: .....

3. Precautions

The patient has a normal cardiac ejection fraction (MUGA Scan or Echocardiogram) ☐ Yes

4. Funded Dose

Please select one of the following schedules:
- ○ 4 mg/kg x 1 IV followed by 2 mg/kg IV weekly
- ○ 8 mg/kg x 1 IV followed by 6 mg/kg IV q3 weeks

- Trastuzumab loading dose of 4 mg/kg x 1, followed by 2 mg/kg IV weekly funded for a maximum of 54 q1 week treatments over a maximum period of 14 months.
- Trastuzumab loading dose of 8 mg/kg x 1, followed by 6 mg/kg IV q3 weeks funded for a maximum of 18 q3 week treatments over a maximum period of 14 months.
- Switching from q1 week regimen to q3 week regimen (and visa versa) is allowed assuming that the actual amount of drug is not exceeded and the 14 month period remains the same.

5. Notes

1. Trastuzumab should not be given concurrently with an anthracycline.

6. 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 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.

iv. **My patient is currently receiving trastuzumab (Herceptin) through the Evidence Building Program (EBP). Can they continue on the reference biologic?**

Yes, patients currently on trastuzumab (Herceptin) through EBP may continue with the reference biologic until their treatment course has ended. However, all new breast cancer patients with node negative HER2-positive tumours less than or equal to 1 cm in size are only eligible for the funding of a trastuzumab biosimilar, consistent with the other NDFP trastuzumab policies. At the discretion of the treating physician or based on individual hospital policy, patients on trastuzumab (Herceptin) may be switched to a trastuzumab biosimilar for the remainder of the funded doses. See FAQ v below.

NOTE: Existing EBP patients who switch from trastuzumab (Herceptin) to a trastuzumab biosimilar will not be funded for further Herceptin treatments.

v. **If my patient is enrolled under the EBP policy, do I need to re-enrol them onto the NDFP policy?**

For patients continuing on trastuzumab (Herceptin) until the end of their treatment course, no further action is required. While the EBP policy has been archived, sites can continue to submit treatment claims for reimbursement. Patients who are switching to a trastuzumab biosimilar for the remainder of their treatment course will be required to submit an enrolment form for funding under the NDFP policy.

7. 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 complete surgical pathology report, stating at minimum: the date of the biopsy; the name of the hospital where the test occurred; the hospital pathology specimen number of the original materials used for the HER2/neu test; the size of the HER2 positive tumour. The results of a FISH/SISH test must be provided if the IHC test result is equivocal.

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

....
Day Month Year

Form 996