Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Trastuzumab (Biosimilar) in combination with Vinorelbine - Metastatic Breast Cancer

This policy version is for trastuzumab biosimilars Herzuma, Kanjinti, Ogivri and Trazimera.

(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 (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:

2. Eligibility Criteria

The patient must meet the following criteria:

a. Her2/neu Status

Patient must test positive for Her2/neu as per Cancer Care Ontario criteria. A photocopy of the pathology report of the Her2/neu test must be submitted to Cancer Care Ontario. The report must state clearly the hospital, date of biopsy and the hospital pathology specimen number of the original material used for the Her2/neu test.

Please specify tests used for detection of Her2/neu:

IHC 3+ ☐ Yes

FISH/ SISH ≥ 2 ☐ Yes

b. Patient has metastatic breast cancer ☐ Yes

c. Patient has progressed with anthracycline or taxane therapy in the adjuvant or metastatic setting ☐ Yes

Note: NDFP funds trastuzumab provided the patient meets funding criteria. The cost of vinorelbine as part of this regimen is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing.

3. Precautions

a. The patient has a normal cardiac ejection fraction ☐ Yes

b. There is no evidence of extensive lung involvement ☐ Yes

4. Funded Dose

- Therapy should be initiated with a loading dose of 4 mg/kg, followed by 2 mg/kg IV weekly
- Patients may be switched to 6 mg/kg IV q3 weeks after they are adequately loaded over a reasonable period of time with weekly dosing

5. Notes

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

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.

7. Supporting Documents

To ensure reimbursement of your claim, both the completed enrolment form and a copy of the required documentation (where applicable) must be submitted through CCO e-Claims.

In the event of an audit, the following should be available to document eligibility:

- A clinic note detailing treatment history and, if requested, MAR confirming treatment was given in combination.

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

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Day Month Year

Form 881