Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Trastuzumab (Biosimilar) with Tucatinib and Capecitabine - 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:

2. Eligibility Criteria

The patient must meet the following criteria:

Trastuzumab (biosimilar) is used in combination with tucatinib and capecitabine for the treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer, including patients with brain metastases. Patients must have received prior treatment with trastuzumab, pertuzumab, and trastuzumab emtansine (T-DM1), separately or in combination, and have a good performance status. ☐ Yes

3. Baseline Information

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

b. Does the patient have brain metastases? ○ Yes ○ No

c. Is the patient transitioning from a private pay or compassionate program? ○ Yes ○ No

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.

[ST-QBP regimen code: CAPETUCA + TRAS]

Trastuzumab is funded in combination with tucatinib and capecitabine, with the recommended doses as follows:

- Tucatinib 300 mg orally twice daily;
- Capecitabine 1000 mg/m^2 orally twice daily on days 1 to 14 of every 21-day cycle.

5. Notes

1. Please refer to the Ministry of Health's Exceptional Access Program (EAP) for full reimbursement criteria for tucatinib when used in combination with trastuzumab and capecitabine for advanced breast cancer. Please check that your patient will be eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration in the Trillium Drug Program.

2. Treatment with trastuzumab can continue if tucatinib or capecitabine are discontinued due to unacceptable toxicity.

3. Prior treatment with trastuzumab deruxtecan may be considered as an alternative to trastuzumab emtansine (T-DM1) for funding purposes.

6. FAQs

1. **My patient is currently receiving a trastuzumab biosimilar, tucatinib and capecitabine that is paid for privately (e.g., patient support program, private insurance, etc.). Can my patient be transitioned to receive funding for a trastuzumab biosimilar 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 of a trastuzumab biosimilar through the NDFP. Please submit as a prior approval request in eClaims including the most recent clinic note outlining the response to treatment, if able to assess.

2. **My patient is currently receiving therapy with single agent capecitabine. Can a trastuzumab biosimilar and tucatinib be added?**

   Provided the patient has not progressed on treatment, and meets all the eligibility criteria, the addition of a trastuzumab biosimilar may be funded under this policy, in combination with tucatinib funded by EAP. 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.

Supporting Documents

None required at time of enrolment.

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

- Pathology report demonstrating HER2-positivity.
- Clinic note(s) outlining treatment history.

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

....
Day Month Year

Form 1003