Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Trastuzumab Emtansine - Unresectable Locally Advanced or Metastatic 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

* The patient meets the following criteria ☐ Yes

- Trastuzumab emtansine is used for the **second line** treatment of HER2-positive, unresectable locally advanced or metastatic breast cancer. The patient has an ECOG performance status of 0 or 1, and has either received prior treatment with trastuzumab plus chemotherapy in the metastatic setting or had disease recurrence during or within 6 months of completing adjuvant therapy with trastuzumab plus chemotherapy.

4. Funded Dose

Trastuzumab emtansine 3.6mg/kg IV every 3 weeks until disease progression or unacceptable toxicity.

5. Notes

1. Publicly funded second line options include one of the following: “trastuzumab emtansine" OR “trastuzumab-other chemotherapy” OR “lapatinib-capecitabine.” Trastuzumab emtansine will not be funded as a third (or later line) option if disease progression has occurred from the other second line options.

2. A complete pathology report (with the date of biopsy, staging information, positive HER2 test results) must be submitted if no prior documentation has been submitted to Ontario Health (Cancer Care Ontario) for trastuzumab funding.

3. There is a risk of medication errors between trastuzumab emtansine and trastuzumab. Do not substitute trastuzumab emtansine for or with trastuzumab. Do not exceed the recommended trastuzumab emtansine dose (i.e., 3.6 mg/kg IV every 3 weeks). The trastuzumab emtansine dose should not be re-escalated after a dose reduction is made.

4. It is recommended that the left ventricular ejection fraction (LVEF) be greater than or equal to 50% prior to initiation of therapy. It is also recommended that LVEF be assessed (via MUGA or ECHO) prior to the initiation of trastuzumab emtansine and at regular intervals (e.g., every 3 months) during treatment. If, at routine monitoring, the LVEF is ≤ 40%, or is 40-45% with a 10% or greater absolute decrease below the pre-treatment value, withhold the trastuzumab emtansine and repeat the LVEF assessment within approximately 3 weeks. Trastuzumab emtansine should be permanently discontinued if the LVEF has not improved or has declined further.

6. 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.

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

....
Day Month Year

Form 869