Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Trastuzumab Emtansine - Adjuvant Treatment for Early 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 (complete 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

a. The patient must meet the following criteria:

Trastuzumab emtansine is used for the adjuvant treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive early breast cancer, who have residual disease after preoperative systemic treatment including trastuzumab. ☐ Yes

3. Baseline Information

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

b. Is the patient transitioning from non-publicly funded means (e.g. private payer or compassionate program)? ○ Yes ○ No

c. If yes, how many cycles did the patient complete prior to the transition? ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13

3. Funded Dose

Trastuzumab emtansine 3.6 mg/kg intravenously (IV) once every 21 days.

Treatment should be continued up to a maximum of 14 cycles, until disease progression, or unacceptable toxicity (whichever occurs first).

[ST-QBP regimen code: KADC]

4. Notes

1. Patients who have not undergone surgery or have not received neoadjuvant trastuzumab are ineligible for trastuzumab emtansine funding under this policy.

2. Patients who progress on or within 6 months of completing trastuzumab emtansine therapy for early breast cancer will not be eligible for trastuzumab emtansine for advanced breast cancer.

3. There is a risk of medication errors between trastuzumab deruxtecan, trastuzumab emtansine, and trastuzumab. Do not substitute or interchange any of the three medications for each other.

5. FAQs

1. **My patient recently completed adjuvant therapy with trastuzumab. Can I now treat my patient with trastuzumab emtansine?**

   Patients who have already completed 1 year (18 cycles) of adjuvant trastuzumab will not be eligible for trastuzumab emtansine funding under this policy.

2. **Can I start my patient on trastuzumab emtansine as neoadjuvant therapy?**

   Trastuzumab emtansine will only be funded after the patient has had surgery for their primary breast cancer.

3. **If my patient cannot tolerate adjuvant trastuzumab emtansine, can they switch back to adjuvant trastuzumab to complete treatment?**

   For patients who experience unacceptable toxicity to adjuvant trastuzumab emtansine, NDFP will fund a switch to trastuzumab monotherapy. In this scenario, patients will be eligible for 18 combined cycles of anti-HER2 therapy (trastuzumab plus trastuzumab emtansine).

4. **My patient has recurred with advanced breast cancer at least 6 months after the last dose of trastuzumab emtansine. Is my patient eligible for anti-HER2 therapy for advanced breast cancer?**

   Patients who develop HER2-positive advanced breast cancer at least 6 months after the last dose of trastuzumab emtansine may be eligible for up to 3 lines of anti-HER2 therapy for advanced disease, according to current funding criteria.

5. **My patient progressed during or within 6 months of the last dose of trastuzumab emtansine. Is my patient eligible for anti-HER2 therapy for advanced breast cancer?**

   Patients who progress during adjuvant trastuzumab emtansine therapy (or within 6 months of the last dose of adjuvant trastuzumab emtansine) will not be eligible for trastuzumab emtansine for advanced breast cancer. However, patients may be eligible for up to 3 lines of anti-HER2 therapy for advanced breast cancer, according to current funding criteria.

6. 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:

- Clinic notes outlining patient and treatment history/response.
- Surgical pathology report indicating residual disease after neoadjuvant treatment (including trastuzumab)

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

....
Day Month Year