Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Trastuzumab Deruxtecan - Unresectable Locally Advanced or 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)

.....

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

Trastuzumab deruxtecan is used for the treatment of adult patients with unresectable locally advanced or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have a good performance status. ☐ Yes

Patients must have either:

- Been treated with at least one prior anti-HER2-based regimen for unresectable locally advanced or metastatic disease, OR
- Experienced disease recurrence during or within 6 months of completing neoadjuvant or adjuvant therapy with an anti-HER2-based regimen.

Patients must have not been treated with an anti-HER2 antibody-drug conjugate in the unresectable locally advanced or metastatic setting.

3. Baseline Information

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

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

c. If yes, please indicate the date of the last administered dose _____ _____ _____
Day Month Year

4. Funded Dose

Trastuzumab Deruxtecan 5.4 mg/kg intravenously (IV) every 21 days.

Treatment should continue until disease progression or unacceptable toxicity, whichever comes first.

[ST-QBP regimen code(s): ENHE]

5. Notes

1. Trastuzumab deruxtecan is used as monotherapy.
2. Patients will be eligible for only one of either trastuzumab deruxtecan OR trastuzumab emtansine in the unresectable locally advanced or metastatic setting.
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.

6. FAQs

1. **My patient is currently receiving trastuzumab deruxtecan through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding for trastuzumab deruxtecan 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 through the NDFP.

2. **What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?**

   If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

   Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:
   - A clinic note and imaging from treatment initiation
   - The most recent clinic note and imaging (if applicable).

3. **My patient received trastuzumab emtansine in the adjuvant setting, will they be eligible for trastuzumab deruxtecan as second-line treatment in the metastatic setting?**

   Patients who were treated with an anti-HER2 antibody-drug conjugate (such as trastuzumab emtansine) for early breast cancer may be eligible for trastuzumab deruxtecan in the metastatic setting provided there has been a minimum of 12 months from completion of adjuvant trastuzumab emtansine.

4. **My patient is being treated with trastuzumab deruxtecan for unresectable locally advanced or metastatic HER2-positive breast cancer and is experiencing toxicity. Can they switch to trastuzumab emtansine?**

   Provided there is no evidence of disease progression, patients experiencing toxicity to trastuzumab deruxtecan may switch to trastuzumab emtansine. Please submit as a prior approval request and include a recent clinic note documenting the toxicity and imaging (if available).

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:
- Pathology confirming HER2-positivity as defined by the American Society of Clinical Oncology – College of American Pathologists (ASCO/CAP) guidelines,
- Clinic notes outlining patient and treatment history/response, and
- CT scans demonstrating no disease progression.

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

Day Month Year