Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Trastuzumab Deruxtecan - HER2-low 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 in the treatment of adult patients with unresectable locally advanced or metastatic human epidermal growth factor receptor 2 (HER2)-low breast cancer who have a good performance status. All patients must not have symptomatic spinal cord compression, clinically active central nervous system metastases, or current interstitial lung disease or pneumonitis.

* In addition to the above, the patient must meet one of the following eligibility criteria:

- ○ Hormone receptor (HR)-*negative* breast cancer and treated with a minimum of one prior line of chemotherapy in the metastatic setting.
- ○ HR-*negative* breast cancer with disease recurrence during or within 6 months of completing adjuvant chemotherapy.
- ○ HR-*positive* breast cancer, treated with a minimum of one prior line of chemotherapy in the metastatic setting, as well as treated with a minimum of one prior line of endocrine therapy (ET) and is no longer considered a candidate for further ET.
- ○ HR-*positive* breast cancer with disease recurrence during or within 6 months of completing adjuvant chemotherapy, as well as treated with a minimum of one prior line of ET and is no longer considered a candidate for further ET.

3. Baseline Information

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

b. If the patient progressed after at least one prior line of metastatic therapy, please indicate the previous treatment regimen(s) the patient had received (select all that apply).
- ☐ Conventional chemotherapy (with or without pembrolizumab)
- ☐ Endocrine therapy [monotherapy or in combination with a cyclin dependent kinase (CDK4/6) inhibitor (e.g., palbociclib, ribociclib)]

c. If the patient progressed during or within six months of completing adjuvant therapy, please indicate the previous treatment regimen(s) the patient had received (select all that apply).
- ☐ Conventional (neo)adjuvant chemotherapy (with or without pembrolizumab)
- ☐ Endocrine therapy (monotherapy or in combination with abemaciclib or olaparib)

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

e. If yes, please indicate the funding source
- ○ Private payer
- ○ Manufacturer patient support program

f. 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. HER2-low is defined according to the American Society of Clinical Oncology - College of American Pathologists (ASCO-CAP) guidelines as either:
    - Immunohistochemistry (IHC) score of 1+; OR
    - IHC score of 2+ without amplification by in situ hybridization (ISH).

2. Trastuzumab deruxtecan must be used as monotherapy.

3. Patients who progress on trastuzumab deruxtecan in the metastatic setting will be ineligible for NDFP funded sacituzumab govitecan as a subsequent line of therapy (and vice versa). However, patients who develop intolerance or toxicities while on trastuzumab deruxtecan may switch to sacituzumab govitecan (and vice versa) provided the patient meets the eligibility criteria and has experienced no disease progression.

4. 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. According to the Canadian Agency for Drugs and Technologies in Health’s provisional funding algorithm, patients should follow the treatment options outlined according to their breast cancer classification. Patients will be ineligible for public funding if the patient was treated using therapies for HR-positive, HER2-negative disease then switched to therapies used for triple negative disease (and vice versa). If new information regarding the patient’s breast cancer classification becomes available (e.g., a new biopsy with updated biomarker results), your patient may be eligible to switch. In these circumstances, please submit a prior approval request including the new pathology results and clinic note(s) outlining the revised treatment plan.

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 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; AND
   - The most recent clinic note and imaging (if applicable); AND
   - Pathology report demonstrating HER2-low disease.

   Please note: Patients who meet the NDFP eligibility criteria and are enrolled in the manufacturer's patient support program (PSP) are eligible to receive continued drug supply through the PSP until March 15, 2024, inclusive.

   After this date, patients who met the NDFP eligibility criteria at the point of treatment initiation are eligible to transition to NDFP funding for the remainder of their treatment course. Although sites may enroll their patient onto this policy at any time beforehand, any treatment claims submitted to eClaims that were given on or before the PSP transition date will be denied.

3. **My patient has metastatic triple negative breast cancer and completed a first-line treatment regimen containing pembrolizumab. Reanalysis of the pathology results demonstrate that my patient is HER2-low. Would my patient be eligible for trastuzumab deruxtecan?**

   Patients with metastatic triple negative breast cancer who have completed first-line pembrolizumab (or who progress on treatment) are eligible for trastuzumab deruxtecan if the updated pathology confirms HR-negative, HER2-low disease and all other eligibility criteria are met.

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; AND
- Imaging demonstrating no disease progression; AND
- Pathology report(s) confirming HER2-low positivity and HR status per the ASCO-CAP guidelines.

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

....
Day Month Year