Ontario Health | Santé Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

Trastuzumab Deruxtecan - Previously Treated Advanced or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

(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

Specify Trial:
○ Clinical Trial 1 ○ Clinical Trial 2
○ Clinical Trial 3 ○ Other

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 will be used as monotherapy for the second-line treatment of adult patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior anti-HER2-based regimen and have a good performance status. ☐ Yes

Patients must not have:

- Symptomatic spinal cord compression
- Clinically active central nervous system (CNS) metastases
- Current interstitial lung disease (ILD) or pneumonitis

3. Baseline Information

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

b. Site of primary tumour ○ GEJ ○ Gastric ○ Esophageal

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

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

4. Funded Dose

Trastuzumab deruxtecan 6.4 mg/kg intravenously (IV) every 3 weeks.

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

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

5. Notes

1. Patients who have HER2-positive esophageal adenocarcinoma may be eligible provided they meet all of the eligibility criteria.

2. HER2 re-testing post trastuzumab-based therapy is not required.

6. FAQs

1. **My patient is currently receiving trastuzumab deruxtecan through non-publicly funded means (e.g.,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 (if applicable) from treatment initiation, and
   - The most recent clinic note and imaging (if applicable).

3. **My patient is currently on second-line treatment and has not been previously treated with trastuzumab deruxtecan. Can my patient switch to second-line trastuzumab deruxtecan?**

   On a time limited basis, patients may switch to second-line trastuzumab deruxtecan provided they meet all eligibility criteria. Please submit a prior approval request which includes a clinic note(s) outlining the patient's treatment history and reasoning for the switch.

4. **My patient is currently receiving third-line or later treatment and has not been previously treated with trastuzumab deruxtecan. Will my patient be eligible for NDFP funding of trastuzumab deruxtecan?**

   On a time limited basis, if your patient has not been previously treated with trastuzumab deruxtecan, they may be eligible for NDFP funding provided they meet all of the other eligibility criteria. Please submit a prior approval request which includes a clinic note(s) outlining the patient's treatment history.

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.
- CT scans demonstrating no disease progression.
- Pathology confirming HER2-positive disease.

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

....
Day Month Year