Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Trastuzumab (Biosimilar) - Advanced or Recurrent Endometrial 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)

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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:

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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 is used as a primary or subsequent-line of treatment for patients with advanced (stage III-IV) or recurrent (any previous stage) human epidermal growth factor receptor 2 (HER2)-positive serous endometrial cancer. ☐ Yes

3. Baseline Information

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

b. Line of therapy ○ Primary treatment ○ Subsequent line of treatment

c. Is the patient transitioning from a non-publicly funded program? ○ Yes ○ No

4. Funded Dose

Trastuzumab at a loading dose of 8 mg/kg intravenously (IV) on Day 1 of the first cycle followed by 6 mg/kg IV every 3 weeks until disease progression or unacceptable toxicity.

The first six cycles are given in combination with carboplatin and paclitaxel followed by trastuzumab monotherapy as maintenance therapy.

[ST-QBP regimen codes: CRBPPACL+TRAS for the induction portion followed by TRAS maintenance]

5. Notes

1. Trastuzumab, in combination with carboplatin and paclitaxel, followed by trastuzumab maintenance is funded in patients with advanced (stage III-IV) or recurrent (any previous stage) HER2-positive serous endometrial cancer, not both.

6. FAQs

i. **My patient is currently receiving trastuzumab through non-publicly funded means for HER2-positive serous endometrial cancer. Can my patient be transitioned over 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 trastuzumab funding through NDFP. Please submit as a prior approval request including the most recent clinic note and imaging (if applicable) documenting the response to treatment (if able to assess).

ii. **My patient is currently receiving chemotherapy with carboplatin and paclitaxel for HER2-positive serous endometrial cancer. Can trastuzumab be added?**

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 the addition of trastuzumab. Please submit as a prior approval request including the most recent clinic note and imaging (if applicable) documenting the response to treatment (if able to assess).

iii. **Will the reimbursement rate be the same for all trastuzumab biosimilars?**

Reimbursement prices for trastuzumab biosimilars are located on our price lists which can be accessed via the eClaims Resource Library.

Any incentives or promotions accepted by hospitals related to purchase and/or selection decisions of trastuzumab will be interpreted as lowering the local acquisition cost of trastuzumab, and, consistent with other NDFP policies, are subject to recovery.

Supporting Documents

None required at the time of enrolment.

In the event of an audit or upon request, the following should be available to document eligibility:

- Clinic note(s) documenting the treatment history.
- A copy of the pathology report demonstrating HER2 overexpression (IHC2+ [confirmed by FISH], or IHC3+). The report must clearly state the hospital, date of biopsy and the hospital pathology specimen of the original material used for the test.
- A copy of the pathology report(s) supporting a diagnosis of serous endometrial cancer.

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

..... ____ .....
Day Month Year