Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pertuzumab with Trastuzumab (Biosimilar) - Unresectable Locally Recurrent 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)

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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:

.....

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

The patient meets the following criteria:

* For use in combination with a taxane for the treatment of patients with HER2 positive unresectable locally recurrent or metastatic breast cancer with an ECOG status of 0 or 1, who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. ☐ Yes

3. Baseline Information

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

b. Please select the taxane to be used in combination with pertuzumab and trastuzumab. ○ Docetaxel ○ Paclitaxel ○ Nab-paclitaxel

4. Funded Dose

Loading dose of pertuzumab 840mg and trastuzumab 8mg/kg, followed every 3 weeks thereafter by a dose pertuzumab 420mg and trastuzumab 6mg/kg, until disease progression or unmanageable toxicity.

[ST-QBP regimen codes: DOCE+PERT+TRAS, NPAC+PERT+TRAS, NPAC(W)+PERT+TRAS, PACL+PERT+TRAS, PACL(W)+PERT+TRAS, PERT+TRAS]

5. Notes

1. Existing patients with an enrolment and treatment claim(s) submitted in eClaims prior to December 15, 2022 will be eligible for continued funding of trastuzumab (Herceptin) in combination with pertuzumab until their treatment course has completed. Sites are required to use the Perjeta-Herceptin combo packs in order to be reimbursed.

   As of September 15, 2022, sites may start using a trastuzumab biosimilar in combination with pertuzumab for new and existing patients. As of December 15, 2022, all new starts must use a trastuzumab biosimilar in combination with pertuzumab. Perjeta is available as single vials.

2. HER2 positive tumour status is confirmed either by IHC (score of 3+) and/or FISH/SISH/ISH (ratio of ≥ 2). A copy of the pathology report must be uploaded in eClaims. The results of the FISH/SISH/ISH test must also be provided if the IHC test result is equivocal.

3. The patient must have a baseline left ventricular ejection fraction (LVEF) of ≥ 50% (as determined by a MUGA scan or ECHO). It is recommended that a MUGA scan or ECHO be repeated every 3 months during treatment to ensure that the LVEF is within the institution's normal limits.

4. Pertuzumab is funded when given in combination with trastuzumab and a taxane. If the taxane is discontinued (e.g., after 6-8 cycles or due to unmanageable toxicity), continued treatment with pertuzumab-trastuzumab will be funded provided there is no evidence of disease progression while on treatment.

5. If the time between two sequential infusions is 6 weeks or more, re-load with an initial dose of 840 mg pertuzumab and 8 mg/kg trastuzumab, followed every 3 weeks thereafter by a dose of 420 mg pertuzumab and 6 mg/kg trastuzumab.

6. FAQs

i. **My patient is currently being treated with pertuzumab in combination with trastuzumab (Herceptin). Can my patient stay on the reference biologic (i.e., trastuzumab (Herceptin))?**

   Yes, patients currently on pertuzumab in combination with trastuzumab (Herceptin) or who initiated treatment before December 15, 2022, may continue with the reference biologic until their treatment course has ended.

   Patients who are continuing treatment with pertuzumab in combination with trastuzumab (Herceptin) after December 15, 2022, must have an enrolment form and treatment claim(s) submitted in eClaims prior to December 15, 2022, to be eligible for continued reimbursement of pertuzumab in combination with trastuzumab (Herceptin). **Effective December 15, 2022, all new patient starts for this indication must be with pertuzumab in combination with a trastuzumab (biosimilar). As of December 15, 2022, NDFP will no longer accept new pertuzumab-trastuzumab (Herceptin) treatments for newly-enrolled patients.**

ii. **My patient is currently receiving pertuzumab in combination with trastuzumab (Herceptin). Can my patient be switched to a trastuzumab biosimilar for the remainder of their treatment course?**

   At the discretion of the treating physician or based on individual hospital policy, patients currently on pertuzumab in combination with trastuzumab (Herceptin) may be switched over to pertuzumab in combination with a trastuzumab biosimilar for the remainder of their treatment course.

   NOTE: Existing patients can switch from Herceptin to a trastuzumab biosimilar; however, patients who switch to a trastuzumab biosimilar will not be funded for further Herceptin treatments.

7. Supporting Documents

Pathology report demonstrating HER2 overexpression (by IHC2+ [and confirmed by FISH+], or IHC3+, if not previously submitted) must be uploaded at time of enrolment.

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

- A recent clinic note and, if available, imaging to confirm stable disease on pertuzumab-trastuzumab.
- A copy of the MAR confirming pertuzumab and trastuzumab was given in combination with a taxane.

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

....
Day Month Year