Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

# Bevacizumab (Biosimilar) with Paclitaxel and Carboplatin - Front-line Treatment (Previously Untreated) Ovarian, Fallopian Tube, and Primary Peritoneal Cancer

(This form must 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

The patient must meet the following criteria:

a. Bevacizumab is given in combination with paclitaxel and carboplatin for the front-line treatment of epithelial ovarian, Fallopian tube or primary peritoneal cancer patients with high risk of relapse (stage III sub-optimally debulked, or stage III unresectable, or stage IV patients); AND ☐ Yes
b. Patient has Eastern Cooperative Oncology Group performance status (ECOG) <= 2

Clarification

Sub-optimal debulking is defined as patients who have > 1 cm of residual disease after debulking surgery.

## 3. Baseline Information

a. Disease stage prior to starting treatment ○ Stage III suboptimally debulked ○ Stage III unresectable ○ Stage IV

b. ECOG PS at the time of enrolment ○ 0 ○ 1 ○ 2

## 4. Funded Dose

Bevacizumab 7.5 mg/kg every 3 weeks as an intravenous infusion.

Bevacizumab will be funded with cycles 2-6 of chemotherapy, and as maintenance treatment for up to 12 additional cycles or until disease progression, whichever comes first (i.e., a maximum of 17 bevacizumab cycles per patient [1 cycle = 1 dose]).

## 5. Notes

1. Bevacizumab is only funded if used in combination with carboplatin and paclitaxel given together once every 3 weeks (CRBPPACL+BEVA).
2. Funding is for a maximum of 17 cycles of bevacizumab or until disease progression, whichever comes first.
3. CCO will fund **one line** of bevacizumab therapy (i.e., **either** front-line bevacizumab **or** bevacizumab in the platinum-resistant recurrent setting, but not both).
4. As per the August 2, 2017 memo, please see below for the following policy clarifications:
    a. Patients who are receiving neoadjuvant chemotherapy (i.e., are receiving chemotherapy prior to a planned interval debulking) are not eligible to receive bevacizumab prior to surgery.
    b. If a patient has stage III disease and was initially deemed to be unresectable, but subsequently becomes optimally debulked, the patient is not eligible for bevacizumab post-surgery.
    c. After definitive surgery, patients are eligible for bevacizumab if the patient is rendered to be sub-optimally debulked (i.e., at least one nodule > 1 cm remaining after debulking) or deemed unresectable.
    d. Stage IV patients (at the time of primary diagnosis) who have planned interval debulking surgery are eligible for bevacizumab after surgery.
    e. The surgical assessment by a gynecological oncologist should be documented and may be requested by NDFP in the event of an audit.
5. When bevacizumab is used in combination with paclitaxel for front-line treatment (previously untreated) ovarian cancer, the cost of paclitaxel is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing.

## 6. FAQs

i. ***My patient is currently receiving bevacizumab through private means. Can my patient be transitioned over to receive funding through the New Drug Funding Program?***
Provided the funding criteria were met at the time of treatment initiation and your patient has not progressed, your patient may be eligible for continued coverage of bevacizumab through the New Drug Funding Program, which will fund the remaining doses of bevacizumab to complete the recommended total of 17 doses of bevacizumab per patient or until disease progression, whichever occurs first.

ii. ***My patient has started carboplatin/paclitaxel and I would like to add bevacizumab. Would NDFP allow this addition?***
The decision to add bevacizumab to carboplatin/paclitaxel should be based on a discussion between the clinician and patient. On a time-limited basis, patients who started chemotherapy prior to the funding announcement and are still on chemotherapy will have the option to add bevacizumab for the remaining cycles of chemotherapy and subsequent cycles of maintenance bevacizumab treatment, provided that funding criteria are met and the disease has not progressed.

iii. ***My patient has started a chemotherapy regimen other than carboplatin/paclitaxel and I would like to switch them to carboplatin/paclitaxel/bevacizumab. Would NDFP fund this switch?***
The decision to switch chemotherapy regimens and add bevacizumab should be based on a discussion between the clinician and patient. On a time-limited basis, patients who started chemotherapy prior to the funding announcement and are still on chemotherapy will have the option to switch to carboplatin/paclitaxel and add bevacizumab for the remaining cycles of chemotherapy and subsequent cycles of maintenance bevacizumab treatment, provided that funding criteria are met and the disease has not progressed.

iv. ***Can I use chemotherapy regimens other than carboplatin and paclitaxel in combination with bevacizumab?***
The only chemotherapy regimen that will be funded in combination with bevacizumab will be carboplatin and paclitaxel given together once every 3 weeks (coded as CRBPPACL+BEVA in the Systemic Treatment-Quality Based Procedure regimen list).

v. ***I would like to use more than 1 cycle of chemotherapy before adding bevacizumab. How will my patient's funding be affected?***
NDFP will fund the addition of bevacizumab at a later date provided that funding criteria are met at the time of treatment initiation and the patient's disease has not progressed on chemotherapy. If disease progression has occurred, the treatment will be considered second line and the patient will not be eligible for bevacizumab coverage.

vi. ***I want to use more than 6 cycles of chemotherapy with bevacizumab. How will my patient's funding be affected?***
The number of chemotherapy cycles used should be based on a discussion between the treating physician and the patient. The maximum number of funded doses of bevacizumab per patient is 17 (unless disease progression occurs first) regardless of the number of cycles of chemotherapy given.

vii. ***My patient is unable to tolerate 6 cycles of chemotherapy. Will maintenance bevacizumab be funded if it is started earlier?***
The decision to discontinue chemotherapy should be a based on a discussion between the treating physician and the patient. Should all chemotherapy be discontinued before 6 cycles are completed, the New Drug Funding Program will fund maintenance bevacizumab if it is started earlier, up to a maximum of 12 cycles or until disease progression, whichever occurs first.

viii. ***If my patient has toxicity to one of the chemotherapy agents (e.g. carboplatin), can I drop that drug while continuing the other drug with bevacizumab?***
Bevacizumab is not funded if your patient is not able to receive paclitaxel and carboplatin at the time of bevacizumab initiation.
If your patient is initially treated with bevacizumab-paclitaxel-carboplatin, but
1. Carboplatin is dropped, NDFP will continue to fund bevacizumab and the Systemic Treatment Quality-Based Procedure (ST-QBP) will continue to fund paclitaxel.
2. Paclitaxel is dropped, the site must upload screenshots or other medication administration records that illustrate bevacizumab treatments being given in combination with carboplatin in order to receive bevacizumab funding for the remainder of the induction treatment.

If disease progression occurs while on a reduced regimen (scenarios i, ii), your patient will no longer be eligible to receive funding for bevacizumab.

ix. ***I would like to start my patient on bevacizumab before adding chemotherapy. How will my patient's eligibility be affected?***
Bevacizumab will not be funded if bevacizumab treatment is initiated before chemotherapy is started.

x. ***Can I use bevacizumab in combination with carboplatin and paclitaxel as neoadjuvant therapy before debulking surgery?***
Patients who are deemed to be surgically resectable or eligible for neoadjuvant therapy at initial diagnosis will not be eligible to receive bevacizumab funding through the New Drug Funding Program.

xi. ***How does this drug/regimen relate to other funded agents for ovarian cancer?***
Patients who use bevacizumab in the front-line setting may be eligible for downstream funding of NDFP drugs funded for platinum sensitive relapse and subsequent platinum resistant relapse.

## 7. Supporting Documents

None required for this policy.
In the absence of collecting supporting documentation at the time of enrolment:

- CCO reserves the right to perform an audit of patient eligibility.
- In the event of an audit, CCO may request the following:
    - Consult note at initial diagnosis indicating the patient's disease status/after surgery if surgery was completed
    - Surgical pathology report indicating disease histology
    - CT scans of the abdomen, pelvis and/or chest indicating stable disease (as per RECIST 1.1 criteria) every 3 months while on treatment

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

Day Month Year

*Form 885*