Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Bevacizumab (Biosimilar) for Platinum-Resistant Recurrent Ovarian, Fallopian Tube, or 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)

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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 must meet the following criteria:

- Bevacizumab is used in combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received no more than two prior anticancer regimens AND ☐ Yes
- The patient has good performance status and no contraindications** to bevacizumab.
- The patient's disease is NOT primary platinum refractory. (Primary platinum refractory refers to disease that has progressed while on front-line platinum-based chemotherapy.) ☐ Yes

Contraindications to bevacizumab **may include a history of bowel obstruction related to underlying disease; history of abdominal fistula, GI perforation or intra-abdominal abscess; evidence of tumour on the rectosigmoid; prior radiotherapy to the pelvis or abdomen; surgery within 4 weeks before starting treatment; untreated CNS disease or symptomatic CNS metastases; history or evidence of thrombotic or hemorrhagic disorders within 6 months of starting treatment; uncontrolled hypertension; active clinically significant cardiovascular disease; non-healing wound, ulcer, or bone fracture.

On a time-limited basis (until October 5, 2018), CCO will fund bevacizumab for patients who had missed an opportunity to use bevacizumab under the platinum-resistant setting, provided that the patient continues to have good performance status, no contraindications to bevacizumab (that would make the patient more susceptible to GI perforation or other adverse events), and the disease is not primary platinum refractory. Patients who have received NDFP funding for front-line bevacizumab are not eligible for the time-limited funding. A clinic note confirming the above needs to be submitted to CCO as part of the enrolment. Please note that this time-limited funding has ended as of October 6, 2018.

3. Baseline Information

a. Histology ○ Clear cell ○ Endometroid ○ Serous ○ Mucinous

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

c. Ascites at baseline ○ Yes ○ No

d. Bevacizumab will be used with the following chemotherapy
- ○ Paclitaxel (PACL(W)+BEVA)
- ○ Pegylated liposomal doxorubicin (PGLDX+BEVA)
- ○ Topotecan 4mg/m^2 q3/4w (TOPO(W)+BEVA)
- ○ Topotecan 1.25mg/m^2 (TOPO+BEVA)

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

e. Date of last systemic treatment for ovarian, fallopian, or primary peritoneal cancer

4. Funded Dose

Please select one of the following regimens:

- ○ Bevacizumab 10mg/kg every 2 weeks when given with pegylated liposomal doxorubicin, paclitaxel, or topotecan (as part of TOPO(W)+BEVA).
- ○ Bevacizumab 15mg/kg every 3 weeks when given with topotecan (as part of TOPO+BEVA).

- Treatment is funded until disease progression or unacceptable toxicity.

5. Notes

1. pCODR noted that the patients in the AURELIA trial were carefully selected to avoid the risk of GI perforations. Careful patient selection and appropriate informed consent for treatment are essential. pCODR also felt that it was very important that physicians provide their patients with a detailed description of the risk of GI perforations prior to commencing treatment with bevacizumab.
2. 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).
3. CCO will fund bevacizumab with chemotherapy for patients with new platinum-resistant disease who may have received prior treatments during the platinum-sensitive stage of their disease, provided the patient has good performance status and no contraindications to bevacizumab.
4. When bevacizumab is used in combination with paclitaxel or topotecan for platinum-resistant ovarian cancer, the costs of paclitaxel and topotecan are funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and are included in the band level pricing.
5. Platinum resistance is defined as clinical or radiological disease progression within 6 months following platinum-based therapy.
6. Bevacizumab must be initiated with chemotherapy. In the event of toxicity requiring discontinuation of an agent, CCO will fund continuation of therapy with the remaining agent(s).
7. CCO will fund bevacizumab when used with one of the following regimens -
    a. bevacizumab 10mg/kg every 2 weeks with paclitaxel 80mg/m^2 on Days 1, 8, 15, 22 every 4 weeks [ST-QBP: PACL(W)+BEVA];
    b. bevacizumab 10mg/kg every 2 weeks with pegylated liposomal doxorubicin 40mg/m^2 Day 1 every 4 weeks [ST-QBP:PGLDX+BEVA];
    c. bevacizumab 10mg/kg every 2 weeks with topotecan 4mg/m^2 Days 1, 8, 15 every 4 weeks [ST-QBP: TOPO(W)+BEVA];
    d. bevacizumab 15mg/kg every 3 weeks with topotecan 1.25mg/m^2 Days 1 to 5 every 3 weeks [ST-QBP: TOPO+BEVA].

6. FAQs

i. ***My patient is currently receiving bevacizumab (Avastin) for platinum-resistant recurrent ovarian, fallopian tube, and primary peritoneal cancer. Can my patient stay on the reference biologic (i.e., bevacizumab (Avastin))?***

Yes, patients currently on bevacizumab (Avastin), or initiated on bevacizumab (Avastin) before November 1, 2019 for this indication may continue with the reference biologic until their treatment course has ended.

ii. ***Is bevacizumab (Mvasi) funded for Platinum-Resistant Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer?***

Bevacizumab (Zirabev or Mvasi) are both funded biosimilars for new patients and those continuing on treatment with bevacizumab for platinum-resistant ovarian, fallopian tube, or primary peritoneal cancer.

iii. ***My patient is currently receiving bevacizumab (Avastin). Can my patient be switched to bevacizumab biosimilar (Mvasi or Zirabev) for the remainder of their treatment cycles?***

At the discretion of the treating physician or based on individual hospital policy, patients currently on bevacizumab (Avastin) may be switched over to a bevacizumab biosimilar for the remainder of their funded doses for the specific indication. If the patient is already enrolled in an NDFP policy for bevacizumab, please re-enroll the patient in the updated bevacizumab enrolment form in order to submit treatments for bevacizumab (Mvasi or Zirabev).

NOTE: Existing patients can switch from Avastin to a bevacizumab biosimilar or from one biosimilar product to another; however, patients who switch from Avastin to a bevacizumab biosimilar will not be funded for further Avastin treatments. **If patients are switching from an existing funded biosimilar to a newly funded biosimilar, please re-enroll the patient in the updated bevacizumab enrolment form in order to submit treatments for the newly funded product.**

iv. ***My patient's disease has remained platinum-sensitive even after multiple treatments with chemotherapy. When my patient's disease becomes platinum-resistant, will they be eligible for bevacizumab?***

CCO will fund bevacizumab for patients with new platinum-resistant disease regardless of the treatments the patient may have received during the platinum-sensitive stage of the disease, provided the patient has good performance status and no contraindications to bevacizumab. Note that CCO will only fund one line of bevacizumab (i.e., either front-line bevacizumab or bevacizumab in the platinum-resistant recurrent setting, but not both).

v. ***My patient has been treated with front-line bevacizumab (e.g., for ovarian cancer) under the New Drug Funding Program. Is my patient eligible to receive bevacizumab under the new platinum-resistant policy?***

CCO will fund one line of bevacizumab (i.e., either front-line bevacizumab or bevacizumab in the platinum-resistant recurrent setting, but not both).

vi. ***My patient is currently receiving their first platinum-resistant regimen. If I add bevacizumab, will CCO fund this?***

The decision to add bevacizumab should be based on a discussion between the physician and patient. CCO will fund the addition of bevacizumab provided the patient meets the funding criteria. Note that CCO will only fund one line of bevacizumab (i.e., either front-line bevacizumab or bevacizumab in the platinum-resistant recurrent setting, but not both).

vii. ***My patient is currently not able to tolerate chemotherapy. Can I start my patient with bevacizumab single agent and then add the chemotherapy later on?***

CCO funding for bevacizumab is contingent on bevacizumab being initiated with chemotherapy. In the event of toxicity requiring discontinuation of an agent however, CCO will fund the continuation of therapy with the remaining agents (as patients in the AURELIA trial were also allowed to continue with the remaining agent(s)).

7. Supporting Documents

For patients being enrolled in bevacizumab in combination with paclitaxel (PACL(W)BEVA),

- A MAR showing the ST-QBP regimen is required.

For patients being enrolled under the time-limited funding,

- A clinic note confirming that the patient continues to have a good performance status and no contraindications to bevacizumab and the disease is not primary platinum-refractory must be submitted with the enrolment.

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

- A clinic note documenting the systemic treatments received, date of disease progression.
- Relevant CA-125 levels and imaging (CT scan) may be requested to confirm eligibility.

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

....
Day Month Year

Form 884