

Bevacizumab (Biosimilar) - Metastatic Colorectal, Small Bowel, or Appendiceal 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 (m²): * 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

- To be used as combination therapy with the FOLFIRI, FOLFOX orXELOX regimens for the first-line treatment of metastatic colorectal, small bowel, or appendiceal cancer (or second-line treatment for patients who received pembrolizumab as first-line treatment); or
- To be used with fluoropyrimidine (AVEX) for the first-line treatment of patients with metastatic colorectal, small bowel, or appendiceal cancer (or second-line treatment for patients who received pembrolizumab as first-line treatment) for whom combination chemotherapy with oxaliplatin or irinotecan is unsuitable, and patient has an ECOG Performance Status < 2.

The patient must meet the following criteria:

- a. The patient has metastatic _____ cancer: Colon Rectal Small bowel
 Appendiceal
- b. The patient is being treated in the first line setting Yes No
- c. The patient is receiving one of the following regimens as per NDFP criteria:
 FOLFIRI FOLFOX XELOX AVEX (ST-QBP: CAPE+BEVA)

3. Baseline Information

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

4. Funded Dose

Please select one of the following regimens: Bevacizumab 5 mg/kg q14 days (with FOLFIRI or FOLFOX)
 Bevacizumab 7.5 mg/kg q21 days (with XELOX or AVEX)

5. Notes

1. To be used in combination with FOLFIRI, FOLFOX, XELOX, or AVEX regimens only. Not reimbursed as a single agent. Not reimbursed if used in other lines of therapy or if used for other indications.
2. Switches between bevacizumab and panitumumab will only be considered within the first 3 months of starting therapy with either agent, provided there is no disease progression on treatment. Patients will only be approved for one switch (i.e. from bevacizumab to panitumumab or vice versa). Please upload a clinic note indicating the reason(s) for switching. If chemotherapy with panitumumab is initiated and proximity to planned surgery is noted as the contraindication, subsequent treatment with bevacizumab will not be funded, regardless of the patient's final surgical status. In addition, in this setting, panitumumab as a single agent will not be funded as a subsequent line of therapy.
3. Patients whose disease progresses on panitumumab in combination with chemotherapy are not eligible for subsequent treatment with bevacizumab.

6. FAQs

- i. ***My patient is receiving bevacizumab (biosimilar) for metastatic colorectal, small bowel, or appendiceal cancer. Is there still a requirement for imaging to be provided every 12 cycles indicating disease response or stable disease as a condition of ongoing funding?***

Imaging will not be required to be uploaded every 12 cycles for patients being treated with bevacizumab (biosimilar). Sites must continue to provide imaging for patients who continue treatment with bevacizumab (Avastin).

7. Supporting Documents

None required at the time of enrolment.

- For patients switching between chemotherapy regimens:
 - A clinic note detailing the rationale for the switch and a recent CT scan indicating that the patient has not progressed on current treatment.

In the event of an audit, CCO may request relevant documentation for this drug and/or policy. Documentation requirements will be communicated at the time of audit.

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

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Day Month Year