

Cetuximab with Irinotecan - 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:
- | | |
|---|---|
| <input type="radio"/> 1-Unknown primary (submit pathology report and clinic note) | <input type="radio"/> 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below) |
| <input type="radio"/> 3-Regimen modification - schedule (complete questions a and b) | <input type="radio"/> 4-Regimen modification - drug substitutions (complete questions a and c) |
| <input type="radio"/> 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f) | <input type="radio"/> 6-Maintenance therapy delay (submit clinic note) |
| <input type="radio"/> 7-Prior systemic therapy clinical trials (complete question g) | <input type="radio"/> 8-Modification due to supply interruption/drug shortage |
| <input type="radio"/> 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 ☐ Yes
introduce drug at a
later date?

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. The patient has metastatic _____ cancer
- ☐ Colon
☐ Rectal
☐ Small bowel
☐ Appendiceal
- b. The patient has failed chemotherapy regimens containing oxaliplatin and irinotecan ☐ Yes
- c. The tumour has non-mutated (wild-type) RAS oncogene ☐ Yes
- d. Cetuximab will be used in combination with irinotecan ☐ Yes

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 for cetuximab:

- ☐ Loading dose of 400 mg/m² IV, followed by weekly 250 mg/m² IV until disease progression
☐ 500 mg/m² every 2 weeks (no loading dose)

Please select one of the following regimens for irinotecan:

- ☐ 350 mg/m² IV every 3 weeks ☐ 180 mg/m² every 2 weeks
☐ 125 mg/m² on days 1, 8, 15 and 22 every 6 weeks

5. Notes

1. Treatments administered prior to RAS testing will not be reimbursed.
2. A copy of the RAS test result must be provided to the NDFP.
3. If the patient experiences intolerance to this regimen and the physician would like to use panitumumab, please submit a Prior Approval request for panitumumab in eClaims along with relevant documentation for review.
4. Patients are eligible for one line of EGFR inhibitor-based therapy guided by biomarker findings (e.g., panitumumab with multi-agent chemotherapy, panitumumab in combination with encorafenib, cetuximab in combination with encorafenib, single agent panitumumab, or cetuximab in combination with irinotecan).
5. Irinotecan is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing.

6. Supporting Documents

The following supporting clinical documents must be submitted to Cancer Care Ontario before treatments begin:

- A copy of the RAS testing results indicating RAS wild-type status.

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

- A clinic note detailing treatment history and, if requested, MAR confirming treatment was given in combination.

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

.....
Day Month Year

Form 977