

- 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

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 who previously received panitumumab in combination with chemotherapy are not eligible for subsequent treatment with cetuximab.
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):

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Day Month Year