Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Cetuximab - In Combination with Encorafenib for Previously Treated Metastatic Colorectal Cancer

(This form should 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:

Cetuximab is used in combination with encorafenib for patients with previously treated BRAF V600E-mutated metastatic colorectal cancer (mCRC). ☐ Yes

Treatment is only for patients who have received at least one previous systemic treatment for mCRC, have good performance status, adequate organ function, and have not received prior EGFR or BRAF inhibitors.

3. Baseline Information

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

b. Is the patient transitioning from a private pay or compassionate program? ○ Yes ○ No

4. Funded Dose

Cetuximab intravenously (IV) once weekly or every 2 weeks in combination with encorafenib*.

Treatment should continue until confirmed disease progression or unacceptable toxicity, whichever comes first.

*The recommended dose of encorafenib for this indication is 300 mg orally once daily.

[ST-QBP regimen code: ENCO+CETU]

Please select the approved dosing schedule for cetuximab (used in combination with encorafenib):

○ Loading dose of 400 mg/m² IV, followed by 250 mg/m² IV once weekly
○ 500 mg/m² IV every 2 weeks (no loading dose)

5. Notes

1. Please refer to the Ministry of Health's Exceptional Access Program for full reimbursement criteria for encorafenib when used in combination with cetuximab for mCRC.

2. 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).

3. In the event encorafenib or cetuximab is discontinued due to unacceptable toxicity, the other drug must also be discontinued.

4. Patients with metastatic small bowel adenocarcinoma or appendiceal adenocarcinoma who meet all other funding criteria may be considered for cetuximab funding under this policy.

6. FAQs

1. **My patient is currently receiving cetuximab in combination with encorafenib for mCRC that is paid for by alternate means (e.g., patient support program, private insurance). Can my patient be transitioned over to receive funding for cetuximab through the New Drug Funding Program (NDFP)?**

   Provided the eligibility criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for continued coverage of cetuximab (in combination with encorafenib) through the NDFP. Please submit as a prior approval request including the most recent clinic note documenting the response to treatment along with the biomarker report confirming a BRAF V600E mutation.

2. **My patient with RAS wild-type mCRC is currently receiving treatment with cetuximab in combination with irinotecan, or single-agent panitumumab. Can I switch my patient to encorafenib in combination with cetuximab?**

   On a time-limited basis and provided all other eligibility criteria are met, NDFP can fund a switch to cetuximab (in combination with encorafenib) provided the patient has not progressed on an EGFR inhibitor-based therapy. Please submit as a prior approval request with clinic note(s) that document the patient's clinical and treatment history, including confirmation that the patient's disease has not yet progressed, along with the biomarker report confirming a BRAF V600E mutation.

3. **What funded treatment options are available for my patient with BRAF V600E mutation positive and microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) mCRC?**

   As per the CADTH provisional funding algorithm, patients may be eligible for pembrolizumab in the first-line setting, followed by encorafenib in combination with an EGFR inhibitor-based therapy (e.g., cetuximab or panitumumab) as a second-line or third-line option depending on sequencing of other therapies.

4. **Will my patient be eligible for funding of encorafenib in combination with cetuximab for BRAF mutations other than V600E?**

   As the pivotal trial was limited to patients with the BRAF V600E mutation, funding cannot be generalized to patients with other BRAF V600 mutations or in those whose BRAF status cannot be determined.

Supporting Documents

Biomarker report confirming a BRAF V600E mutation must be uploaded at the time of enrolment.

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

- Clinic notes documenting treatment history and response to prior therapies.
- Pathology report confirming colorectal cancer.

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

....
Day Month Year

Form 978