Regimen Monograph

 Regimen Name
 Drug Regimen
 Cycle Frequency
 Premedication and Supportive Measures
 Dose Modifications
 Adverse

 Effects
 Interactions
 Drug Administration and Special Precautions
 Recommended Clinical Monitoring
 Administrative

 Information
 References
 Other Notes
 Disclaimer

A - Regimen Name

MFOLFOX6+ENCO+CETU Regimen

Fluorouracil-Leucovorin-Oxaliplatin-Encorafenib-Cetuximab

Disease Site Gastrointestinal

Colorectal

Intent Palliative

Regimen Category

Evidence-informed:

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

This **Regimen Abstract** is an **abbreviated** version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Rationale and Uses

Treatment for patients with previously untreated BRAF-V600E mutated metastatic colorectal cancer

back to top

B - Drug Regimen

cetuximab	500 mg /m²	IV	Day 1
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(This drug is not currently publicly funded for this regimen and intent)

oxaliplatin 85 mg/m² IV over 2 hours Day 1

leucovorin 400 mg /m² IV over 2 hours Day 1

(concurrently with

oxaliplatin)

fluorouracil 400 mg /m² IV bolus, after Day 1

leucovorin

THEN

fluorouracil 2400 mg /m² IV continuous infusion Start on Day 1

over 46 hours (single

dose)

encorafenib 300 mg PO Days 1 to 14

(This drug is not currently publicly funded for this regimen and intent)

back to top

C - Cycle Frequency

REPEAT EVERY 14 DAYS

Until disease progression or unacceptable toxicity

back to top

D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate

Low – No routine prophylaxis; PRN recommended (encorafenib)

• Also refer to <u>CCO Antiemetic Recommendations</u>.

Screen for hepatitis B virus in all cancer patients starting systemic treatment. Refer to the <u>hepatitis B virus screening and management</u> guideline.

Cetuximab Premedications (prophylaxis for infusion reaction):

- H1-receptor antagonist (e.g. diphenhydramine 50 mg IV) 30-60 minutes prior to the dose.
- Corticosteroid IV 30-60 minutes prior to the dose.
- Consider discontinuing pre-medications after the 2nd infusion based on clinical judgment and the presence/severity of IR.

Other Supportive Care:

- Avoid mucositis prophylaxis with ice chip as cold temperatures can precipitate or exacerbate acute neurological symptoms of oxaliplatin.
- Patients should use sun protection while receiving cetuximab and for 2 months after treatment completion.
- Consider pre-emptive therapy for EGFR inhibitor-related skin toxicity; the following was shown to be of benefit with panitumumab treatment, starting the day before treatment and continued until week 6. (Lacouture et al, 2010):
 - Skin moisturizer applied to the face, hands, feet, neck, back and chest in the morning
 - Sunscreen to exposed areas (SPF ≥ 15, UVA and UVB) before going outdoors
 - Hydrocortisone 1% cream to the face, hands, feet, neck, back and chest at bedtime
 - Doxycycline (or minocycline) PO
- Refer to the Canadian recommendations for the management of skin rash during EGFRtargeted monoclonal antibody treatment for GI malignancies. (Melosky et al, 2009)

back to top

.J -	Admi	nistrative	• Inforn	nation

Approximate Patient Visit

5 hours

back to top

K - References

Elez E, Yoshino T, Shen L, et al. Encorafenib, cetuximab, and mFOLFOX6 in *BRAF*-mutated colorectal cancer. N Engl J Med 2025;392(24):2425-37. doi: 10.1056/NEJMoa2501912.

December 2025 new ST-QBP regimen

back to top

M - Disclaimer

Regimen Abstracts

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Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Regimen Monographs

Refer to the <u>New Drug Funding Program</u> or <u>Ontario Public Drug Programs</u> websites for the most up-to-date public funding information.

The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

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Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

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back to top