Regimen Monograph

A - Regimen Name

CRBPFU+CETU Regimen

CARBOplatin-Fluorouracil-Cetuximab

Disease Site Head and Neck

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.

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B - Drug Regimen

Cycle 1:

cetuximab	400 mg /m²	IV	Day 1 ONLY
CARBOplatin	AUC 5	IV	Day 1
fluorouracil	1000 mg /m²/day	IV 24h continuous infusion	Daily, on days 1 to 4
cetuximab	250 mg /m²	IV	Days 8, 15

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

Cycles 2 to 6:

CARBOplatin	AUC 5	IV	Day 1
fluorouracil	1000 mg /m²/day	IV 24h continuous infusion	Daily, on days 1 to 4
cetuximab	250 mg /m²	IV	Days 1, 8, 15

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

Note: Report as regimen code CETU when used as maintenance after chemotherapy portion is complete

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For a maximum of 6 cycles of CRBPFU+CETU until disease progression or unacceptable toxicity

After six cycles, patients with at least stable disease may continue to receive weekly maintenance cetuximab until disease progression or unacceptable toxicity.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate + NK1 antagonist (Carboplatin AUC ≥ 5) (Day 1)
Minimal (Days 8, 15)

Other Supportive Care:
An H1 antagonist (e.g. 50 mg of diphenhydramine IV) is recommended with each dose of cetuximab.

Also refer to CCO Antiemetic Recommendations.

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J - Administrative Information

Pharmacy Workload (average time per visit)	29.431 minutes
Nursing Workload (average time per visit)	71.458 minutes

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K - References

Vermorken JB, Mesia R, Rivera F, et al. Platinum-based chemotherapy plus cetuximab in head and neck cancer. N Engl J Med. 2008 Sep 11;359(11):1116-27.

Yoshino T, Hasegawa Y, Takahashi S, et al. Platinum-based chemotherapy plus cetuximab for the first-line treatment of Japanese patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck: results of a phase II trial. Jpn J Clin Oncol. 2013 May;43(5):524-31.

April 2023 Updated DPD deficiency and fluorouracil antidote information in Other Notes section.

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L - Other Notes

DPD Deficiency

Patients should be tested for DPD deficiency before starting treatment with fluorouracil. Refer to the DPD Deficiency Guidance for Clinicians for more information.

In patients with unrecognized DPD deficiency, acute, life-threatening toxicity may occur; if acute grade 2-4 toxicity develops, treatment should be stopped immediately and permanent discontinuation considered based on clinical assessment of the toxicities.

Antidote for Fluorouracil Overdose:

Uridine triacetate is a prodrug of uridine and is a specific antidote for treating fluorouracil overdose or severe early onset toxicities. If available, consider administering as soon as possible (i.e. within 96 hours) for suspected overdose. If not available, treatment is symptomatic and supportive.

For usage approval and supply, contact Health Canada's Special Access Program (SAP) (Phone: 613-941-2108. On-call service is available for emergencies). Uridine triacetate (Vistogard®) is supplied by its manufacturer in the United States (Wellstat Therapeutics).

The recommended dosing and administration for **uridine triacetate** in patients ≥18 years is:

- 10 grams (1 packet of coated granules) orally every 6 hours for 20 doses in total, without regards to meals.
- Granules should not be chewed. They should be mixed with 3 to 4 ounces of soft foods such as applesauce, pudding or yogurt.
- The dose should be ingested within 30 minutes of preparation, followed by at least 4 ounces of water.
- Refer to the prescribing information on dose preparation for NG-tube or G-tube use.

Additional resources on the management of fluorouracil infusion overdose:

- Management of Fluorouracil Infusion Overdose Guideline (Alberta Health Services)
- Management of Fluorouracil Infusion Overdose at the BCCA - Interim Guidance (BC Cancer Agency)

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M - Disclaimer

Regimen Abstracts

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Regimen Monographs

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

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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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