Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Administrative Information |
References | Other Notes | Disclaimer

A - Regimen Name

CAPECRBP+CETU Regimen

Capecitabine-Carboplatin-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

developed.

Supplementary Public Funding

capecitabine

ODB - General Benefit (capecitabine)

B - Drug Regimen

Cycle 1:

<u>cetuximab</u> 400 mg /m² IV Day 1 ONLY

cetuximab 250 mg /m² IV Days 8, 15

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

CARBOplatin AUC 5 IV Day 1

Adjust Carboplatin dose to AUC target (using Calvert formula) as outlined in "Other Notes" section.

capecitabine 1000 mg /m² PO BID*; Days 1 to 14

(Total dose 2000 mg/m²/day) (Available as 150 mg or 500 mg tablets)

Cycles 2 to 6:

cetuximab 250 mg /m² IV Days 1, 8, 15

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

CARBOplatin AUC 5 IV Day 1

Adjust Carboplatin dose to AUC target (using Calvert formula) as outlined in "Other Notes" section.

capecitabine 1000 mg/m² PO BID; Days 1 to 14

(Total dose 2000 mg/m²/day) (Available as 150 mg or 500 mg tablets)

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

C - Cycle Frequency

REPEAT EVERY 21 DAYS

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

After 6 cycles, patients with at least stable disease may continue to receive weekly maintenance cetuximab until disease progression or unacceptable toxicity.

back to top

D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate + NK1 antagonist (Carboplatin AUC ≥ 5) (D1)

Minimal (D8, 15)

No routine prophylaxis for capecitabine

Other Supportive Care:

Also refer to CCO Antiemetic Summary

- Topical emollients (e.g. hand creams, udder balm) therapy may ameliorate the manifestations of hand-foot syndrome in patients receiving capecitabine.
- Supportive care should be provided, including loperamide for diarrhea.

back to top

J - Administrative Information

Approximate Patient Visit Carboplatin and Cetuximab: 2 hours; Cetuximab: 1.5

hours

Pharmacy Workload (average time per visit) 22.22 minutes

Nursing Workload (average time per visit) 44.16 minutes

K - References

Hitt R, Jimeno A, Rodríguez-Pinilla M, et al. Phase II trial of cisplatin and capecitabine in patients with squamous cell carcinoma of the head and neck, and correlative study of angiogenic factors. Br J Cancer. 2004 Dec 13; 91(12): 2005–2011.

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 information in the Other Notes section

back to top

L - Other Notes

DPD Deficiency:

Patients should be tested for DPD deficiency before starting treatment with capecitabine. 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.

Calvert Formula:

DOSE (mg) = target AUC X (GFR + 25)

- AUC = product of serum concentration (mg/mL) and time (min)
- GFR (glomerular filtration rate) expressed as measured Creatinine Clearance or estimated from Serum Creatinine (by Cockcroft and Gault method or Jelliffe method)

(Calvert AH, Newell DR, Gumbrell LA, et al, Carboplatin dosage: Prospective evaluation of a simple formula based on renal function. J Clin Oncol, 1989; 7: 1748-1756)

back to top

M - Disclaimer

Regimen Abstracts

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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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