Regimen Monograph

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

A - Regimen Name

CAPECISP+CETU Regimen

Capecitabine-Cisplatin-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.

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)

CISplatin 100 mg /m² IV Day 1

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)

<u>CISplatin</u> 100 mg /m² IV Day 1

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

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For a maximum of 6 cycles of CAPECISP+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.

D - Premedication and Supportive Measures

Antiemetic Regimen: High (D1)

Minimal (D8, 15)

No routine prophylaxis for capecitabine

Other Supportive Care:

Standard regimens for Cisplatin premedication and hydration should be followed. Refer to local guidelines.

Also refer to CCO Antiemetic Summary

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J - Administrative Information

Approximate Patient Visit Cisplatin and Cetuximab: 4 hours; Cetuximab only: 2

hours

Pharmacy Workload (average time per visit) 36.087 minutes
Nursing Workload (average time per visit) 41.667 minutes

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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

L - Other Notes

Patients should be tested for DPD deficiency before starting treatment with capecitabine. Refer to the <u>DPD Deficiency Guidance for Clinicians</u> 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.

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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.

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