Regimen Monograph

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

A - Regimen Name

XELOX+PEMB Regimen

Capecitabine (Xeloda®)-Oxaliplatin-Pembrolizumab

Disease Site

Gastrointestinal
Esophagus

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

First-line treatment, in patients with good performance status, of:

- locally advanced unresectable or metastatic esophageal adenocarcinoma or squamous cell carcinoma
- HER2-negative advanced or metastatic adenocarcinoma of the esophagogastric junction

Supplementary Public Funding	**pembrolizumab** New Drug Funding Program (Pembrolizumab - First-line Treatment of Advanced Esophageal and Esophagogastric Junction Carcinoma) (NDFP Website) **capecitabine** ODB - General Benefit (capecitabine) (ODB Formulary)

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B - Drug Regimen

pembrolizumab[1,2]	2 mg /kg	IV (max 200 mg)	Day 1
oxaliplatin	130 mg /m²	IV	Day 1
capecitabine^	1000 mg /m²	PO	BID, Days 1 to 14

(^Total dose 2000 mg/m^2/day)

[1]Dosing based on NDFP funding criteria. Refer to NDFP form for alternative pembrolizumab dosing schedule (4 mg/kg IV q6 weeks).

[2]Give pembrolizumab before chemotherapy when given on the same day.

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C - Cycle Frequency

XELOX: Repeat every 21 days
Until disease progression or unacceptable toxicity^

PEMBROLIZUMAB: Repeat every 21 days (2 mg/kg)†
Until disease progression or unacceptable toxicity, or up to a maximum of 2 years, whichever occurs first

^If chemotherapy is discontinued after at least 1 cycle due to intolerance, pembrolizumab may be continued as single agent (PEMB(MNT)) for up to 2 years, unless disease progression or unacceptable toxicity.

†Alternative pembrolizumab dosing schedule is 4 mg/kg IV q 42 days.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate
No routine prophylaxis for capecitabine

Other Supportive Care:

- 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.

Also refer to CCO Antiemetic Recommendations.

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J - Administrative Information

Outpatient prescription for home administration (capecitabine)

Approximate Patient Visit	3 hours
Pharmacy Workload (average time per visit)	26.390 minutes
Nursing Workload (average time per visit)	54.167 minutes

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K - References

Cunningham D, Starling N, Rao S, et al. Capecitabine and oxaliplatin for advanced esophagogastric cancer. N Engl J Med 2008;358(1):36-46. doi: 10.1056/NEJMoa073149.

pCODR reimbursement review (pembrolizumab: esophageal carcinoma, gastroesophageal junction adenocarcinoma). February 2022.

Sun JM, Shen L, Shah MA, et al. Pembrolizumab plus chemotherapy versus chemotherapy alone for first-line treatment of advanced oesophageal cancer (KEYNOTE-590): a randomised, placebo-controlled, phase 3 study. Lancet 2021;398(10302):759-71.

April 2023 Updated DPD deficiency information in the Other Notes section

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L - Other Notes

DPD Deficiency Testing and Guidance:

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.

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M - Disclaimer

Regimen Abstracts

A 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). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

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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.

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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