

## Regimen Monograph

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## A - Regimen Name

# CAPECISP+PEMB Regimen

Capecitabine-CISplatin-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**

**Cycles 1 to 6:**

<a href="#">pembrolizumab</a> <sup>1</sup>	2 mg /kg	IV (max 200 mg)	Day 1
<a href="#">CISplatin</a>	80 mg /m <sup>2</sup>	IV	Day 1
<a href="#">capecitabine</a> <sup>^</sup>	1000 mg /m <sup>2</sup>	PO	BID Days 1 to 14

(<sup>^</sup>Total dose 2000 mg/m<sup>2</sup>/day)

**Cycles 7 and onwards:**

<a href="#">pembrolizumab</a> <sup>1</sup>	2 mg /kg	IV (max 200 mg)	Day 1
<a href="#">capecitabine</a> <sup>^,†</sup>	1000 mg /m <sup>2</sup>	PO	BID Days 1 to 14

(<sup>^</sup>Total dose 2000 mg/m<sup>2</sup>/day)

<sup>†</sup>May continue with PEMB(MNT) if capecitabine is discontinued. Refer to PEMB(MNT) regimen for details.

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

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## C - Cycle Frequency

**CAPECISP or CAPE:** Repeat every 21 days

**PEMBROLIZUMAB:** Repeat every 21 days (2 mg/kg)<sup>†</sup>

For 6 cycles of CAPECISP+PEMB<sup>^</sup>, followed by CAPE+PEMB<sup>^</sup> for up to 2 years (including initial CAPECISP+PEMB cycles), unless disease progression or unacceptable toxicity.

<sup>^</sup>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.

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

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## D - Premedication and Supportive Measures

**Antiemetic Regimen:** High (Cycles 1-6)  
Low – No routine prophylaxis; PRN recommended (Cycles 7+)

### Other Supportive Care:

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

Also refer to [CCO Antiemetic Recommendations](#).

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## J - Administrative Information

Approximate Patient Visit	4 hours
Pharmacy Workload (average time per visit)	40.337 minutes
Nursing Workload (average time per visit)	54.833 minutes

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## K - References

Kang YK, Kang WK, Shin D, et al. Capecitabine/cisplatin versus 5-fluorouracil/cisplatin as first-line therapy in patients with advanced gastric cancer: a randomised phase III noninferiority trial. *Ann Oncol* 2009;20(4):666-73.

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 Aug 28;398(10302):759-771.

**April 2023** Updated DPD deficiency information in the Other Notes section

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## L - Other Notes

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.*

*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-*

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QBP regimen as they are developed.

### **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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