

## Regimen Monograph

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## A - Regimen Name

# CAPECISP+NIVL Regimen

Capecitabine-CISplatin-Nivolumab

**Disease Site**      Gastrointestinal  
                              Esophagus  
                              Gastric / Stomach

**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 of HER2-negative unresectable advanced or metastatic gastric, esophagogastric junction, or esophageal adenocarcinoma

**Supplementary Public Funding** [nivolumab](#)  
 New Drug Funding Program (Nivolumab - First-line Treatment of Advanced Gastric, Esophageal, and Esophagogastric Junction Adenocarcinoma) ([NDFP Website](#) )

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### B - Drug Regimen

<a href="#">nivolumab</a> <sup>1, 2</sup>	4.5 mg /kg	IV (max 360 mg)	Day 1; q21 days
<a href="#">CISplatin</a>	80 mg /m <sup>2</sup>	IV	Day 1
<a href="#">capecitabine</a> *	1000 mg /m <sup>2</sup>	PO	BID Days 1 to 14

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

<sup>1</sup> Give nivolumab before chemotherapy when given on the same day.

<sup>2</sup> Dosing based on NDFP funding criteria. Refer to NDFP form for alternative nivolumab dosing schedule (3 mg/kg IV q14 days; maximum dose 240 mg).

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### C - Cycle Frequency

**CAPECISP<sup>^</sup>**: Repeat every 21 days, until disease progression or unacceptable toxicity occurs; usually up to 6 cycles due to cumulative cisplatin toxicity

**NIVOLUMAB<sup>^</sup>**: Repeat every 21 days (4.5 mg/kg)<sup>†</sup> for up to 2 years (including doses given with CAPECISP), unless disease progression or unacceptable toxicity, whichever occurs first

<sup>^</sup>If chemotherapy is discontinued after at least 1 cycle due to intolerance, nivolumab may be continued as single agent (Refer to NIVL(MNT)) for up to 2 years, unless disease progression or unacceptable toxicity.

<sup>†</sup>Alternative nivolumab dosing schedule is 3 mg/kg IV q14 days.

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## D - Premedication and Supportive Measures

**Antiemetic Regimen:** High (CAPECISP)

### 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)	39.187 minutes
Nursing Workload (average time per visit)	54.833 minutes

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## K - References

Bang YJ, Van Cutsem E, Feyereislova A, et al. Trastuzumab in combination with chemotherapy versus chemotherapy alone for treatment of HER2-positive advanced gastric or gastro-oesophageal junction cancer (ToGA): a phase 3, open-label, randomised controlled trial. *Lancet* 2010; 376(9742): 687-97.

CADTH Reimbursement Recommendation: Nivolumab (For the treatment of adult patients with human epidermal growth factor receptor 2–negative advanced or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma). March 2022.

Janjigian YY, Shitara K, Moehler M, et al. First-line nivolumab plus chemotherapy versus chemotherapy alone for advanced gastric, gastro-oesophageal junction, and oesophageal adenocarcinoma (CheckMate 649): a randomised, open-label, phase 3 trial. *Lancet* 2021 Jul 3;398(10294):27-40.

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.

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**PEBC Advice Documents or Guidelines**

- [Systemic Therapy for Advanced Gastric and Gastro-Esophageal Carcinoma](#)

**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**

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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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