

## Regimen Monograph

[Regimen Name](#) | [Drug Regimen](#) | [Cycle Frequency](#) | [Premedication and Supportive Measures](#) | [Administrative Information](#) | [References](#) | [Other Notes](#) | [Disclaimer](#)

## A - Regimen Name

# CISPGEMC(W)+PEMB Regimen

Cisplatin-Gemcitabine-Pembrolizumab

**Disease Site**      Gastrointestinal  
Hepatobiliary / Liver / Bile Duct

**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 patients with locally advanced unresectable or metastatic biliary tract cancer

Refer to NDFP form for funding details.

**Supplementary** [pembrolizumab](#)**Public Funding**

New Drug Funding Program (Pembrolizumab - Locally Advanced Unresectable or Metastatic Biliary Tract Cancer) ([NDFP Website](#) )

[back to top](#)

**B - Drug Regimen**

<a href="#">pembrolizumab</a> <sup>1,2</sup>	2 mg /kg	IV (max 200 mg)	Day 1
<a href="#">gemcitabine</a>	1000 mg /m <sup>2</sup>	IV	Days 1 and 8
<a href="#">CISplatin</a>	25 mg /m <sup>2</sup>	IV	Days 1 and 8

<sup>1</sup> Give pembrolizumab prior to chemotherapy when both are given on the same day.

<sup>2</sup> Dosing based on NDFP funding criteria. Refer to NDFP form for alternative pembrolizumab dosing schedule (4 mg/kg IV q6 weeks).

[back to top](#)

**C - Cycle Frequency****REPEAT EVERY 21 DAYS**

For up to 8 cycles, followed by maintenance GEMC+PEMB(MNT)<sup>^</sup> or PEMB(MNT)<sup>^</sup>, unless disease progression or unacceptable toxicity occurs

<sup>^</sup>Pembrolizumab may be continued as single agent (PEMB(MNT)) for up to a total of 2 years, if chemotherapy is discontinued after at least 1 cycle due to intolerance.

Refer to NDFP form for funding criteria for retreatment.

[back to top](#)

## D - Premedication and Supportive Measures

**Antiemetic Regimen:** Moderate

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

**Screen for hepatitis B virus in all cancer patients starting systemic treatment.** Refer to the [hepatitis B virus screening and management](#) guideline.

### **Pembrolizumab Premedication (prophylaxis for infusion reactions):**

- Routine pre-medication is not recommended.
- May consider antipyretic and H1-receptor antagonist in patients who experienced a grade 1-2 infusion reaction.

### **Other Supportive Care:**

- Avoid the use of corticosteroids or immunosuppressants before starting pembrolizumab treatment.
- All patients should receive adequate hydration and premedication for emesis, according to local guidelines.

[back to top](#)

## J - Administrative Information

Approximate Patient Visit	3 hours
Pharmacy Workload (average time per visit)	34.104 minutes
Nursing Workload (average time per visit)	46.667 minutes

[back to top](#)

## K - References

CADTH reimbursement recommendation: pembrolizumab (biliary tract carcinoma). Canadian Journal of Health Technologies 2024;4(7).

CADTH reimbursement review: pembrolizumab (biliary tract carcinoma). Canadian Agency for Drugs and Technologies in Health. December 15, 2023.

Cisplatin drug monograph, Ontario Health (Cancer Care Ontario).

Gemcitabine drug monograph, Ontario Health (Cancer Care Ontario).

Kelley RK, Ueno M, Yoo C, et al. Pembrolizumab in combination with gemcitabine and cisplatin compared with gemcitabine and cisplatin alone for patients with advanced biliary tract cancer (KEYNOTE-966): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2023 Jun 3;401(10391):1853-65.

Okusaka, T, Nakachi K, Fukutomi A, et al. Gemcitabine alone or in combination with cisplatin in patients with biliary tract cancer: a comparative multicentre study in Japan. Br J Cancer 2010;103(4):469-74.

Pembrolizumab drug monograph, Ontario Health (Cancer Care Ontario).

Valle J, Wason H, Palmer DH, et al. Cisplatin plus gemcitabine versus gemcitabine for biliary tract cancer. N Engl J Med 2010; 362(14):1273-81.

**December 2024** Added NDFP form; updated Rationale/Uses, Drug Regimen and Cycle Frequency sections

[back to top](#)

## 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-*

---

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.*

*The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.*

*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.*

*While care has been taken in the preparation of the information contained in the Formulary, 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.*

*CCO and the Formulary's content providers shall have no liability, whether direct, indirect, consequential, contingent, special, or incidental, related to or arising from the information in the Formulary or its use thereof, whether based on breach of contract or tort (including negligence), and even if advised of the possibility thereof. Anyone using the information in the Formulary does so at his or her own risk, and by using such information, agrees to indemnify CCO and its content providers from any and all liability, loss, damages, costs and expenses (including legal fees and expenses) arising from such person's use of the information in the Formulary.*

[back to top](#)