Regimen Monograph

A - Regimen Name

CISPGEMC+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 Public Funding	**pembrolizumab** New Drug Funding Program (Pembrolizumab - Locally Advanced Unresectable or Metastatic Biliary Tract Cancer) (NDFP Website)

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B - Drug Regimen

pembrolizumab [1,2]	2 mg /kg	IV (max 200 mg)	Day 1
gemcitabine	1000 mg /m²	IV	Days 1 and 8
CISplatin	75 mg /m²	IV	Day 1

[1]Give pembrolizumab prior to chemotherapy when both are given on the same day.

[2] 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

REPEAT EVERY 21 DAYS

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

^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.

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D - Premedication and Supportive Measures

Antiemetic Regimen: High (Day 1)
Low (Day 8)

- 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.

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J - Administrative Information

Approximate Patient Visit	Day 1: 4.75 to 5.75 hours; Day 8: 0.75 hours
Pharmacy Workload (average time per visit)	37.77325 minutes
Nursing Workload (average time per visit)	47.91667 minutes

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K - References

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

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

Giuliani F, Gebbia V, Maiello E, et al. Gemcitabine and cisplatin for inoperable and/or metastatic biliary tree carcinomas: a multicenter phase II study of the Gruppo Oncologico dell'Italia Meridionale (GOIM). Ann Oncol 2006 Jun;17 Suppl 7:vii73-7.

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

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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.

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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