Regimen Monograph

A - Regimen Name

GEMC+PEMB(MNT) Regimen

Gemcitabine-Pembrolizumab (Maintenance)

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

For maintenance treatment of patients with locally advanced unresectable or metastatic biliary tract cancer

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

[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

Until disease progression or unacceptable toxicity. Pembrolizumab may be given up to a maximum of 2 years (35 cycles given q3 weeks or 18 doses given q6 weeks), including cycles with initial chemotherapy and pembrolizumab.

(In the clinical trial, there was no limit to the number of cycles of gemcitabine.)

If gemcitabine is discontinued due to intolerance, may continue with single agent pembrolizumab maintenance for a maximum of 2 years of pembrolizumab treatment. Refer to the PEMB(MNT) regimen.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low

- Also refer to CCO Antiemetic Recommendations.

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.

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J - Administrative Information

Approximate Patient Visit	Day 1: 2 hours; Day 8: 0.75 hour
Pharmacy Workload (average time per visit)	22.855 minutes
Nursing Workload (average time per visit)	36.667 minutes

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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.

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

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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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