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 unresectable, locally advanced or metastatic biliary tract cancer, after completion of CISPGEMC(W)+PEMB

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B - Drug Regimen

pembrolizumab[1]	200 mg	IV	Day 1
(This drug is not currently publicly funded for this regimen and intent)			
gemcitabine	1000 mg /m²	IV	Days 1 and 8

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

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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), 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

Other Supportive Care:

- Also refer to CCO Antiemetic Recommendations.
- All patients should receive adequate hydration and premedication for emesis, according to local guidelines.

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

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.

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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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