

Regimen Monograph

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A - Regimen Name

CRBPGEMC+PEMB Regimen

Carboplatin-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 For treatment of patients with unresectable, locally advanced or metastatic biliary tract cancer (for patients who are unable to receive cisplatin)

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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 /m ²	IV	Days 1 and 8
CARBOplatin	AUC 5	IV	Day 1

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

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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

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate + NK1 antagonist (Carboplatin AUC \geq 5) (Day 1)
Low (Day 8)

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:

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

Avoid the use of corticosteroids or immunosuppressants before starting pembrolizumab treatment.

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J - Administrative Information

Approximate Patient Visit	Day 1: 2.75 hours; Day 8: 45 minutes
Pharmacy Workload (average time per visit)	28.715 minutes
Nursing Workload (average time per visit)	42.917 minutes

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K - References

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

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

Julka PK, Puri T, Rath GK, et al. A phase II study of gemcitabine and carboplatin combination chemotherapy in gallbladder carcinoma. *Hepatobiliary Pancreat Dis Int* 2006;5(1):110-4.

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.

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.

Williams KJ, Picus J, Trinkhaus, et al. Gemcitabine with carboplatin for advanced biliary tract cancers: a phase II single institution study. *HPB (Oxford)* 2010;12(6):418-26.

July 2024 new ST-QBP regimen

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L - Other Notes

Calvert Formula

DOSE (mg) = target AUC X (GFR + 25)

- AUC = product of serum concentration (mg/mL) and time (min)
- GFR (glomerular filtration rate) expressed as measured Creatinine Clearance or estimated from Serum Creatinine (by Cockcroft and Gault method or Jelliffe method)

(Calvert AH, Newell DR, Gumbrell LA, et al, Carboplatin dosage: Prospective evaluation of a simple formula based on renal function. J Clin Oncol, 1989; 7: 1748-1756)

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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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