

Regimen Monograph

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A - Regimen Name

CISPGEMC(W)+DURV Regimen

CISplatin-Gemcitabine-Durvalumab

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 the first-line treatment of locally advanced* or metastatic biliary tract cancer** in patients who have a good performance status

* not amenable to surgery

** patients must have unresectable / metastatic disease at initial diagnosis or > 6 months after completion of adjuvant therapy or curative surgery

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

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B - Drug Regimen

durvalumab ^{1,2}	1500 mg	IV	Day 1
gemcitabine	1000 mg /m ²	IV	Days 1 and 8
CISplatin	25 mg /m ²	IV	Days 1 and 8

¹For patients with body weight ≤ 30 kg, give durvalumab 20 mg/kg, until weight increases to > 30kg.

²Give durvalumab 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, unless disease progression or unacceptable toxicity occurs; refer to DURV(MNT) for durvalumab maintenance

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate

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

Other Supportive Care:

- Also refer to [CCO Antiemetic Recommendations](#).
- All patients should receive adequate hydration and premedication for emesis, according to local guidelines.
- Consider pre-medication in patients with prior durvalumab infusion related reactions.

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J - Administrative Information

Approximate Patient Visit	Day 1: 4 hours; Day 8: 3 hours
Pharmacy Workload (average time per visit)	38.029 minutes
Nursing Workload (average time per visit)	51.667 minutes

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K - References

CADTH reimbursement recommendation: Durvalumab (in combination with gemcitabine-based chemotherapy, for the treatment of patients with locally advanced or metastatic biliary tract cancer), February 2023.

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

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

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

Oh DY, He AR, Qin S, et al. Durvalumab plus gemcitabine and cisplatin in advanced biliary cancer. *NEJM Evidence*. 2022 Jun 1:EVIDo2200015.

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.

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.

April 2024 Modified Rationale and Uses and Cycle Frequency sections; added NDFP form

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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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