Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Administrative Information | References | Other Notes | Disclaimer

A - Regimen Name

CISPGEMC+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 /m²	IV	Days 1 and 8
CISplatin	75 mg /m²	IV	Day 1

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

[2]Give 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: High (Day 1)
Low (Day 8)

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: 0.75 hour
Pharmacy Workload (average time per visit)	37.198 minutes
Nursing Workload (average time per visit)	46.083 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).

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;17 Suppl 7:vii73-7.

Kang MJ, Lee JL, Kim TW, et al. Randomized phase II trial of S-1 and cisplatin versus gemcitabine and cisplatin in patients with advanced biliary tract adenocarcinoma. Acta Oncol 2012;51(7):860-6.

Lee GW, Kang JH, Kim HG, et al. Combination chemotherapy with gemcitabine and cisplatin as first-line treatment for immunohistochemically proven cholangiocarcinoma. Am J Clin Oncol 2006 Apr;29(2):127-31.

Oh DY, He AR, Qin S, et al. Durvalumab plus gemcitabine and cisplatin in advanced biliary cancer. NEJM Evidence. 2022 Jun 1:EVIDoa2200015.

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 Updated administration section with pharmacy and nursing workload.

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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.

The format and content of the drug monographs, regimen monographs, appendices and symptom management

information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

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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