Regimen Monograph

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

A - Regimen Name

CRBPFU+ZOLB Regimen

Carboplatin-Fluorouracil-Zolbetuximab

FU+ZOLB(MNT) Regimen

Fluorouracil-Zolbetuximab (Maintenance)

Disease Site	Gastrointestinal Gastric / Stomach
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	Treatment of CLDN18.2 positive, HER2-negative locally advanced unresectable or metastatic gastric or gastroesophageal

junction adenocarcinoma

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B - Drug Regimen

Cycle 1:

zolbetuximab[1]	800 mg /m²	IV loading dose	Day 1
CARBOplatin	AUC 4 to 5	IV	Day 1
fluorouracil	800 mg /m²/day	IV as continuous infusion	Days 1 to 5

Cycles 2 to 6:

zolbetuximab[1]	600 mg /m²	IV maintenance dose	Day 1
CARBOplatin[2]	AUC 4 to 5	IV	Day 1
fluorouracil[2]	800 mg /m²/day	IV as continuous infusion	Days 1 to 5

Cycle 7 and beyond:

zolbetuximab[1]	600 mg /m²	IV	Day 1
fluorouracil[2]	800 mg /m²/day	IV continuous infusion	Days 1 to 5

[1]Give zolbetuximab before chemotherapy when given on the same day.

[2]After treatment initiation, if chemotherapy is discontinued due to intolerance, zolbetuximab may be continued as single agent - ZOLB(MNT).

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For 6 cycles of CRBPFU+ZOLB, followed by FU+ZOLB(MNT) until disease progression or unacceptable toxicity.

After treatment initiation, if chemotherapy is discontinued due to intolerance, zolbetuximab may be continued as single agent, until disease progression or unacceptable toxicity. (Refer to ZOLB(MNT).)

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D - Premedication and Supportive Measures

Antiemetic Regimen: High (Day 1)
Low (Days 2 to 5 (fluorouracil days))

- Also refer to CCO Antiemetic Recommendations.

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

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J - Administrative Information

Approximate Patient Visit

CRBPFU+ZOLB	Day 1: 4.5 hours; 5-FU only: 0.5 hour
FU+ZOLB(MNT)	0.5

Pharmacy Workload **(average time per visit)**

CRBPFU+ZOLB	23.761 minutes
FU+ZOLB(MNT)	22.05 minutes

Nursing Workload **(average time per visit)**

CRBPFU+ZOLB	60.417 minutes
FU+ZOLB(MNT)	45 minutes

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K - References

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

Dank M, Zaluski J, Barone C, et al. Randomized phase III study comparing irinotecan combined with 5-fluorouracil and folinic acid to cisplatin combined with 5-fluorouracil in chemotherapy naive patients with advanced adenocarcinoma of the stomach or esophagogastric junction. Ann Oncol 2008;19(8):1450-7.

Fluorouracil drug monograph. Ontario Health (Cancer Care Ontario).

Kang YK, Kang WK, Shin D, et al. Capecitabine/cisplatin versus 5-fluorouracil/cisplatin as first-line therapy in patients with advanced gastric cancer: a randomised phase III noninferiority trial. Ann Oncol 2009;20(4):666-73.

Ohtsu A, Shimada Y, Shirao K, et al. Randomized phase III trial of fluorouracil alone versus fluorouracil plus cisplatin versus uracil and tegafur plus mitomycin in patients with unresectable, advanced gastric cancer: The Japan Clinical Oncology Group Study (JCOG9205). J Clin Oncol 2003;21(1):54-9.

Product monograph: Zolbetuximab. Astellas Pharma Canada, Inc. December 14, 2024.

Reimbursement recommendation (draft): Zolbetuximab. Canada' Drug Agency. Meeting Date: December 2024.

Shah MA, Shitara K, Ajani JA, et al. Zolbetuximab plus CAPOX in CLDN18.2-positive gastric or gastroesophageal junction adenocarcinoma: the randomized, phase 3 GLOW trial. Nat Med. 2023 Aug;29(8):2133-41.

Shitara K, Lordick F, Bang YJ, et al. Zolbetuximab plus mFOLFOX6 in patients with CLDN18.2-positive, HER2-negative, untreated, locally advanced unresectable or metastatic gastric or gastro-oesophageal junction adenocarcinoma (SPOTLIGHT): a multicentre, randomised, double-blind, phase 3 trial. Lancet. 2023 May 20;401(10389):1655-68.

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L - Other Notes

DPD Deficiency Testing and Guidance:

Patients should be tested for DPD deficiency before starting treatment with fluorouracil.
Refer to the DPD Deficiency Guidance for Clinicians for more information.

In patients with unrecognized DPD deficiency, acute, life-threatening toxicity may occur; if acute grade 2-4 toxicity develops, treatment should be stopped immediately and permanent discontinuation considered based on clinical assessment of the toxicities.

Antidote for Fluorouracil Overdose:

Uridine triacetate is a prodrug of uridine and is a specific antidote for treating fluorouracil overdose or severe early onset toxicities. If available, consider administering as soon as possible (i.e. within 96 hours) for suspected overdose. If not available, treatment is symptomatic and supportive.

For usage approval and supply, contact Health Canada's Special Access Program (SAP) (Phone: 613-941-2108. On-call service is available for emergencies).

The recommended dosing and administration for **uridine triacetate** in patients ≥18 years is:

- 10 grams (1 packet of coated granules) orally every 6 hours for 20 doses in total, without regards to meals.
- Granules should not be chewed. They should be mixed with 3 to 4 ounces of soft foods such as applesauce, pudding or yogurt.
- The dose should be ingested within 30 minutes of preparation, followed by at least 4 ounces of water.
- Refer to the prescribing information on dose preparation for NG-tube or G-tube use.

Additional resources on the management of fluorouracil infusion overdose:

- Management of Fluorouracil Infusion Overdose Guideline (Alberta Health Services)
- Management of Fluorouracil Infusion Overdose at the BCCA - Interim Guidance (BC Cancer Agency)

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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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