

## Regimen Monograph

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### A - Regimen Name

## CAPECRBP+ZOLB Regimen

Carboplatin-Capecitabine-Zolbetuximab

## CAPE+ZOLB(MNT) Regimen

Capecitabine-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**      Treatment of CLDN18.2 positive, HER2-negative locally advanced

**Uses** unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma

**Supplementary Public Funding** [capecitabine](#)  
ODB - General Benefit (capecitabine) ([ODB Formulary](#) )

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## B - Drug Regimen

### Cycle 1:

<b>zolbetuximab</b> <sup>1</sup>	800 mg /m <sup>2</sup>	IV loading dose	Day 1
(This drug is not currently publicly funded for this regimen and intent)			
<a href="#">CARBOplatin</a>	AUC 4 to 5	IV	Day 1
<a href="#">capecitabine</a>	1000 mg /m <sup>2</sup>	PO	BID*, on Days 1-14

\*Total dose 2000 mg/m<sup>2</sup>/day

### Cycles 2 to 6:

<b>zolbetuximab</b> <sup>1</sup>	600 mg /m <sup>2</sup>	IV maintenance dose	Day 1
(This drug is not currently publicly funded for this regimen and intent)			
<a href="#">CARBOplatin</a> <sup>2</sup>	AUC 4 to 5	IV	Day 1
<a href="#">capecitabine</a> <sup>2</sup>	1000 mg /m <sup>2</sup>	PO	BID*, on Days 1-14

\*Total dose 2000 mg/m<sup>2</sup>/day

### Cycle 7 and beyond:

<b>zolbetuximab</b> <sup>1</sup>	600 mg /m <sup>2</sup>	IV maintenance dose	Day 1
(This drug is not currently publicly funded for this regimen and intent)			
<a href="#">capecitabine</a> <sup>2</sup>	1000 mg /m <sup>2</sup>	PO	BID*, on Days 1-14

\*Total dose 2000 mg/m<sup>2</sup>/day

<sup>1</sup>Give zolbetuximab before chemotherapy when given on the same day.

<sup>2</sup>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 CAPECRBP+ZOLB, followed by CAPE+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)  
No routine prophylaxis for capecitabine

- 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.

### Other Supportive Care:

- Topical emollients (e.g. hand creams, udder balm) therapy may ameliorate the manifestations of hand-foot syndrome in patients receiving capecitabine.
- Supportive care should be provided, including loperamide for diarrhea.

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## J - Administrative Information

### Approximate Patient Visit

**CAPECRBP+ZOLB** 3.5 to 4 hours

### Pharmacy Workload (average time per visit)

**CAPECRBP+ZOLB** 22.22 minutes

### Nursing Workload (average time per visit)

**CAPECRBP+ZOLB** 44.167 minutes

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## K - References

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

Cisplatin 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.

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.

**March 2025** new ST-QBP regimen

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## L - Other Notes

### **DPD Deficiency Testing and Guidance**

Patients should be tested for DPD deficiency before starting treatment with capecitabine. 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 Capecitabine Overdose:**

**Uridine triacetate** is a prodrug of uridine and is a specific antidote for treating capecitabine 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.

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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.*

*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.*

### 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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