Regimen Monograph

A - Regimen Name

CAPECISP+ZOLB Regimen

Cisplatin-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 Uses	First-line treatment of CLDN18.2 positive, HER2-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (Refer to the NDFP eligibility form for detailed funding criteria.)
Supplementary Public Funding	**zolbetuximab** New Drug Funding Program (Zolbetuximab - First-line Treatment of Advanced Gastric and Gastroesophageal Junction Adenocarcinoma) (NDFP Website) **capecitabine** ODB - General Benefit (capecitabine) (ODB Formulary)

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B - Drug Regimen

Cycle 1:

zolbetuximab[1]	800 mg /m²	IV loading dose	Day 1
CISplatin	80 mg /m²	IV	Day 1
capecitabine	1000 mg /m²	PO	BID*, on Days 1-14

*Total dose 2000 mg/m^2/day

Cycles 2 to 6:

zolbetuximab[1]	600 mg /m²	IV	Day 1
CISplatin	80 mg /m²	IV	Day 1
capecitabine	1000 mg /m²	PO	BID*, on Days 1-14

*Total dose 2000 mg/m^2/day

Cycle 7 and beyond:

zolbetuximab[1]	600 mg /m²	IV	Day 1
capecitabine	1000 mg /m²	PO	BID*, on Days 1-14

*Total dose 2000 mg/m^2/day

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

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

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

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:

- Standard regimens for Cisplatin premedication and hydration should be followed. Refer to local guidelines.
- 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

CAPECISP+ZOLB	6 hours
CAPE+ZOLB(MNT)	3 hours

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

CAPECISP+ZOLB	56.299 minutes
CAPE+ZOLB(MNT)	45.05 minutes

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

CAPECISP+ZOLB	69.833 minutes
CAPE+ZOLB(MNT)	57.50 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.

Reimbursement recommendation: Zolbetuximab. Canada's Drug Agency. February 2025.

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.

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

November 2025 Updated the Administrative Information section

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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

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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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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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