#### Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Dose Modifications | Adverse |
Effects | Interactions | Drug Administration and Special Precautions | Recommended Clinical Monitoring | Administrative |
Information | References | Other Notes | Disclaimer

#### A - Regimen Name

### **OXALRALT+ZOLB Regimen**

Oxaliplatin-Raltitrexed-Zolbetuximab

**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, in patients who cannot receive fluorouracil

(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)

#### raltitrexed

New Drug Funding Program (Raltitrexed - Metastatic Esophageal, Gastroesophageal Junction, or Gastric Cancer) (NDFP Website)

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### **B** - Drug Regimen

### Cycle 1:

zolbetuximab <sup>1</sup>	800 mg /m²	IV loading dose	Day 1
raltitrexed	3 mg /m²	IV	Day 1
oxaliplatin	100-130 mg /m²	IV	Day 1

#### Cycle 2 and beyond:

zolbetuximab <sup>1</sup>	600 mg /m <sup>2</sup>	IV maintenance dose	Day 1
raltitrexed	3 mg /m²	IV	Day 1
oxaliplatin	100-130 mg /m²	IV	Day 1

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

#### C - Cycle Frequency

#### **REPEAT EVERY 21 DAYS**

Until disease progression or unacceptable toxicity

If chemotherapy is discontinued, 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

Also refer to <u>CCO Antiemetic Recommendations</u>.

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

#### **Other Supportive Care:**

• Avoid mucositis prophylaxis with ice chips as cold temperatures can precipitate or exacerbate acute neurological symptoms of oxaliplatin.

#### J - Administrative Information

Approximate Patient Visit 5 hours

Pharmacy Workload (average time per visit) 59.790 minutes

Nursing Workload (average time per visit) 67.50 minutes

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#### K - References

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

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

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 New ST-QBP regimen

#### 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 <u>New Drug Funding Program</u> or <u>Ontario Public Drug Programs</u> 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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