Regimen Monograph

A - Regimen Name

OXALRALT Regimen

Oxaliplatin-Raltitrexed

Disease Site

Gastrointestinal
- Colorectal
- Esophagus
- Gastric / Stomach
- Small bowel and appendix

Intent

Adjuvant
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 adjuvant or palliative treatment of colorectal, small bowel, appendiceal, esophageal, gastroesophageal junction, or gastric cancer

- Funded by NDFP for patients who have complete dihydropyrimidine dehydrogenase (DPD) deficiency, have experienced unacceptable toxicity with 5-FU chemotherapy, live more than 60 km from the treatment centre/hospital, or have special transportation needs

Supplementary Public Funding

raltitrexed
New Drug Funding Program (Raltitrexed - Metastatic Colorectal Small Bowel or Appendiceal Cancer) (NDFP Website)

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

raltitrexed
New Drug Funding Program (Raltitrexed - Adjuvant Colorectal, Small Bowel, or Appendiceal Cancer) (NDFP Website)

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

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B - Drug Regimen

raltitrexed	3 mg /m²	IV	Day 1
oxaliplatin	100 to 130 mg /m²	IV	Day 1

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

Adjuvant: Until disease progression, unacceptable toxicity, or up to a maximum of 8 cycles, whichever comes first

Palliative: Until disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate

- 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.

Oxaliplatin premedication (prophylaxis for infusion reactions):

- There is insufficient evidence that routine prophylaxis with pre-medications reduces IR rates.
- Consider corticosteroids and H1-receptor antagonists ± H2-receptor antagonists in high-risk patients (i.e. ≥ cycle 6, younger age, female gender, prior platinum exposure, platinum-free interval ≥ 3 years).

Other Supportive Care:

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

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J - Administrative Information

Approximate Patient Visit	3 hours
Pharmacy Workload (average time per visit)	25.24 minutes
Nursing Workload (average time per visit)	49.167 minutes

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K - References

BCCA Protocol Summary for Adjuvant Combination Chemotherapy for Node Positive Colon Cancer Using Oxaliplatin and Raltitrexed in Patients Intolerant to Fluorouracil or Capecitabine, Feb 1, 2021.

Cascinu S, Graziano F, Ferraù F, et al. Raltitrexed plus oxaliplatin (TOMOX) as first-line chemotherapy for metastatic colorectal cancer. A phase II study of the Italian group for the study of gastrointestinal tract carcinomas (GISCAD). Annals of Oncology 2002;13:716–20.

Feliu J, Castañón C, Salud A, et al. Phase II randomised trial of raltitrexed-oxaliplatin vs raltitrexed-irinotecan as first-line treatment in advanced colorectal cancer. Br J Cancer 2005;93(11):1230-5.

Fluoropyrimidine Treatment in Patients with Dihydropyrimidine Dehydrogenase (DPD) Deficiency: Guidance for Clinicians. Ontario Health (Cancer Care Ontario), April 2023.

GI Drug Advisory Committee consensus, Ontario Health (Cancer Care Ontario).

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Laudani A, Gebbia V, Leonardi V, et al. Activity and toxicity of oxaliplatin plus raltitrexed in 5-fluorouracil refractory metastatic colorectal adeno-carcinoma. Anticancer Res 2004;24(2C):1139-42.

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Wilson KS , Fitzgerald CA, Barnett JB, et al. Adjuvant therapy with raltitrexed in patients with colorectal cancer intolerant of 5fluorouracil: British Columbia Cancer Agency experience. Cancer Invest 2007;25(8):7114.

April 2023 Modified Disease site, Rationale/uses, Supplementary public funding, and Premedications/supportive care sections

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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

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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.

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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