

## Regimen Monograph

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## A - Regimen Name

# IRINRALT Regimen

Irinotecan-Raltitrexed

**Disease Site**      Gastrointestinal  
                            Colorectal  
                            Esophagus  
                            Gastric / Stomach  
                            Small bowel and appendix

**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**

- For treatment of metastatic 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](#) )

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**B - Drug Regimen**

<a href="#">irinotecan</a>	180* mg /m <sup>2</sup>	IV	Day 1
<a href="#">raltitrexed</a>	3 mg /m <sup>2</sup>	IV	Day 1

\*Irinotecan doses ranging from 180 mg/m<sup>2</sup> to 350 mg/m<sup>2</sup> q3 weeks have been studied in clinical trials.

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**C - Cycle Frequency**

**REPEAT EVERY 21 DAYS**

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.

### Other Supportive Care:

Irinotecan - Cholinergic adverse effects (early diarrhea):

- Prophylactic atropine may be considered in patients who have experienced cholinergic symptoms.
- Diarrhea (including abdominal cramps) may be severe and delayed with Irinotecan; use Loperamide 4mg at the onset of diarrhea, then 2mg q2h until patient is diarrhea-free for 12 hours.
- Loperamide must be provided.

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## J - Administrative Information

Approximate Patient Visit	2.5 hours
Pharmacy Workload (average time per visit)	24.262 minutes
Nursing Workload (average time per visit)	43.333 minutes

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## K - References

Aparicio J, Vicent JM, Maestu I, et al. First-line treatment with irinotecan and raltitrexed in metastatic colorectal cancer. Mature results of a multicenter phase II study. *Oncology* 2005;68(1):58-63.

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Carnaghi C , Rimassa L, Garassino I, et al. Irinotecan and raltitrexed: an active combination in advanced colorectal cancer. *Ann Oncol* 2002;13(9):14249.

Chiara S, Nobile MT, Tomasello L, et al. Phase II trial of irinotecan and raltitrexed in chemotherapy-naive advanced colorectal cancer. *Anticancer Res.* 2005 Mar-Apr;25(2B):1391-6.

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).

Liu M, Jia Q, Wang X, et al. Clinical efficacy of irinotecan plus raltitrexed chemotherapy in refractory esophageal squamous cell cancer. *Anticancer Drugs* 2020;31(4):403-10.

Qu X, Liu Y, Teng Z, et al. The efficacy and safety of irinotecan plus raltitrexed as second-line treatment in advanced colorectal cancer (ACC) patients: A summary analysis of a multicenter, phase II trial. *Ann Oncol* 2021;32 Supplement 5.

Ulrich-Pur H, Raderer M, Kornek GV, et al. Irinotecan plus raltitrexed vs raltitrexed alone in patients with gemcitabine-pretreated advanced pancreatic adenocarcinoma. *Br J Cancer* 2003;88(8):1180-4.

**April 2023** Modified Disease site, Rationale/uses, Supplementary public funding, Drug regimen, 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 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**

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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.*

*The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.*

*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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