

Regimen Monograph

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A - Regimen Name

CRBPFU+TRAS Regimen

Carboplatin-Fluorouracil-Trastuzumab

Disease Site Gastrointestinal
 Esophagus
 Gastric / Stomach

(Gastric and gastroesophageal junction)

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.

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B - Drug Regimen**Note:**

- Different trastuzumab products are **NOT INTERCHANGEABLE**.
- This regimen is to be used for Gastric and Gastroesophageal Junction cancers.

Trastuzumab Loading Dose:

[trastuzumab](#)¹ 8 mg /kg IV Day 1 (Loading dose-
first cycle only)

(Prior authorization is required for PDRP funding of this drug within this regimen)

THEN, Trastuzumab Maintenance Dose:

[trastuzumab](#)¹ 6 mg /kg IV Day 1 (Cycle 2 and
onwards)

(Prior authorization is required for PDRP funding of this drug within this regimen)

¹ In general, the dose of trastuzumab should be delayed if the chemotherapy cycle is delayed for scheduling convenience)

AND

[CARBOplatin](#) AUC 4 to 5 IV Day 1

Adjust Carboplatin dose to AUC target (using Calvert formula) as outlined in the "Other Notes" section.

[fluorouracil](#) 800 mg /m²/day IV over 24 hours as Days 1 to 5
continuous infusion

An alternative **fluorouracil** schedule is 1000 mg/m²/day over 24 hours as IV continuous infusion, on days 1 to 4.

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C - Cycle Frequency**REPEAT EVERY 21 DAYS**

Carboplatin-Fluorouracil: Up to 6 cycles unless evidence of disease progression or unacceptable toxicity occurs

Trastuzumab: Until evidence of disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate + NK1 antagonist (Carboplatin AUC ≥ 5)
Moderate (Carboplatin AUC < 5)

Other Supportive Care:

Also refer to [CCO Antiemetic Recommendations](#).

Trastuzumab: Nausea and vomiting are usually symptoms that are related to infusion-associated reactions. To prevent recurrence of infusion-associated reactions, acetaminophen and diphenhydramine may be given as pre-medication. Refer to [Trastuzumab](#) drug monograph for full details.

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J - Administrative Information

Approximate Patient Visit	First Cycle: 3 hours; Subsequent cycles: 2 hours
Pharmacy Workload (average time per visit)	23.28 minutes
Nursing Workload (average time per visit)	69.583 minutes

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K - References

Bang YJ, Van Cutsem E, Feyereislova A, et al. Trastuzumab in combination with chemotherapy versus chemotherapy alone for treatment of HER2-positive advanced gastric or gastro-oesophageal junction cancer (ToGA): a phase 3, open-label, randomised controlled trial. *Lancet* 2010; 376(9742): 687-97.

PEBC Advice Documents or Guidelines

- [Systemic Therapy for Advanced Gastric and Gastro-Esophageal Carcinoma](#)

April 2023 Updated DPD deficiency and fluorouracil antidote information in the Other Notes section

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L - Other Notes

DPD Deficiency Testing and Guidance:

Patients should be tested for DPD deficiency before starting treatment with fluorouracil. 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.

Calvert Formula:

DOSE (mg) = target AUC X (GFR + 25)

- AUC = product of serum concentration (mg/mL) and time (min)
- GFR (glomerular filtration rate) expressed as measured Creatinine Clearance or estimated from Serum Creatinine (by Cockcroft and Gault method or Jelliffe method)

(Calvert AH, Newell DR, Gumbrell LA, et al, Carboplatin dosage: Prospective evaluation of a simple formula based on renal function. J Clin Oncol, 1989; 7: 1748-1756)

Antidote for Fluorouracil Overdose:

Uridine triacetate is a prodrug of uridine and is a specific antidote for treating fluorouracil 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). Uridine triacetate (Vistogard®) is supplied by its manufacturer in the United States (Wellstat Therapeutics).

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.

Additional resources on the management of fluorouracil infusion overdose:

- [Management of Fluorouracil Infusion Overdose Guideline](#) (Alberta Health Services)
- [Management of Fluorouracil Infusion Overdose at the BCCA - Interim Guidance](#) (BC Cancer Agency)

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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.

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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