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

CRBPGEMC+TISL Regimen

Carboplatin-Gemcitabine-Tislelizumab

Disease Site Head and Neck

Nasopharynx

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 recurrent/metastatic nasopharyngeal cancer

back to top

B - Drug Regimen

tislelizumab 200 mg IV Day 1

(This drug is not currently publicly funded for this regimen and intent)

gemcitabine 1000 mg /m² IV Days 1 and 8

CARBOplatin AUC 5 IV Day 1

back to top

C - Cycle Frequency

REPEAT EVERY 21 DAYS

For 4 to 6 cycles, followed by maintenance tislelizumab (TISL(MNT)), unless disease progression or unacceptable toxicity occurs

back to top

D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate + NK1 antagonist (Carboplatin AUC ≥ 5) (Day 1)

Low (Day 8)

Also refer to CCO Antiemetic Recommendations.

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

back to top

J - Administrative Information

Approximate Patient Visit Day 1: 2 hours; Day 8: 0.75 hour

Pharmacy Workload (average time per visit) 28.472 minutes

Nursing Workload (average time per visit) 46.667 minutes

back to top

K - References

Chi KH, Chang YC, Chan WK, et al. A phase II study of carboplatin in nasopharyngeal carcinoma. Oncology 1997 May-Jun;54(3):203-7.

Yang Y, Pan J, Wang H, et al. Tislelizumab plus chemotherapy as first-line treatment for recurrent or metastatic nasopharyngeal cancer: A multicenter phase 3 trial (RATIONALE-309). Cancer Cell 2023 Jun 12;41(6):1061-72.e4. doi: 10.1016/j.ccell.2023.04.014.

Yang Y, Pan J, Wang H, et al. 1210 RATIONALE 309: A randomized, global, double-blind, phase III trial of tislelizumab (TIS) vs placebo, plus gemcitabine + cisplatin (GP), as first-line treatment for recurrent/metastatic nasopharyngeal cancer (RM-NPC) (Abstract). Ann Oncol 2021;32(Supplement 7):S1430.

Yang H, Lu Y, Xu Z, et al. Gemcitabine plus platinum versus docetaxel plus platinum as first-line therapy for metastatic nasopharyngeal carcinoma: a randomized clinical study. Saudi J Med Med Sci 2021 May-Aug;9(2):125-34.

May 2024 new ST-QBP regimen

back to top

L - Other Notes

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)

back to top

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.

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.

While care has been taken in the preparation of the information contained in the Formulary, 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.

CCO and the Formulary's content providers shall have no liability, whether direct, indirect, consequential, contingent, special, or incidental, related to or arising from the information in the Formulary or its use thereof, whether based on breach of contract or tort (including negligence), and even if advised of the possibility thereof. Anyone using the information in the Formulary does so at his or her own risk, and by using such information, agrees to indemnify CCO and its content providers from any and all liability, loss, damages, costs and expenses (including legal fees and expenses) arising from such person's use of the information in the Formulary.

back to top