Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Administrative Information |
References | Other Notes | Disclaimer

A - Regimen Name

CRBPGEMC+NIVL Regimen

CARBOplatin-Gemcitabine-Nivolumab

Disease Site Lung

Non-Small Cell

Intent Neoadjuvant

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

Neoadjuvant treatment for resectable non-small cell lung cancer in patients with tumours that are ≥ 4 cm in size or are node positive, and who have good performance status.* (An alternative for patients who cannot receive cisplatin)

*Refer to NDFP form for eligibility criteria

Supplementary <u>nivolumab</u>

Public Funding New Drug Funding Program (Nivolumab - Neoadjuvant Treatment for Non-

Small Cell Lung Cancer)

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B - Drug Regimen

nivolumab ¹	4.5 mg /kg	IV (max 360 mg)	Day 1
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gemcitabine 1000 mg /m² IV Days 1 and 8

CARBOplatin AUC 5 to 6 IV Day 1

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For a total of 3 cycles unless disease progression or unacceptable toxicity

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¹Dosing based on NDFP funding criteria

D - Premedication and Supportive Measures

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

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.

Nivolumab Pre-medications (prophylaxis for infusion reaction):

- Routine pre-medication is not recommended.
- May consider pre-medication with antipyretics and H1-receptor antagonists if an IR has occurred in the past.

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J - Administrative Information

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

Pharmacy Workload (average time per visit) 33.34 minutes

Nursing Workload (average time per visit) 45.4167 minutes

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K - References

Carboplatin drug monograph, Ontario Health (Cancer Care Ontario).

Forde PM, Spicer J, Lu S, et al. Neoadjuvant nivolumab plus chemotherapy in resectable lung cancer. N Engl J Med. 2022 May 26;386(21):1973-85.

Gemcitabine drug monograph, Ontario Health (Cancer Care Ontario).

July 2024 new ST-QBP regimen

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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)

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M - Disclaimer

Regimen Abstracts

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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 <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.

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