

Regimen Monograph

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A - Regimen Name

CISPGEMC+NIVL Regimen

CISplatin-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.*

*Refer to NDFP form for eligibility criteria

**Supplementary
Public Funding****[nivolumab](#)**

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
CISplatin	75 mg /m ²	IV	Day 1
gemcitabine	1000-1250 mg /m ²	IV	Days 1 and 8

¹Dosing based on NDFP funding criteria

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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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D - Premedication and Supportive Measures

Antiemetic Regimen: High (D1)
Low (D8)

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.

Pre-medications (prophylaxis for infusion reaction):

Nivolumab

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

Other Supportive Care:

Standard regimens for Cisplatin premedication and hydration should be followed. Refer to local guidelines.

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J - Administrative Information

Approximate Patient Visit	Day 1: 5 hours; Day 8: 0.75 hour
Pharmacy Workload (average time per visit)	37.198 minutes
Nursing Workload (average time per visit)	46.667 minutes

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K - References

Cisplatin and gemcitabine drug monographs, Cancer Care Ontario.

Barlesi F, Chouaid C, Crequit J, et al. A randomized trial comparing adjuvant chemotherapy with gemcitabine plus cisplatin with docetaxel plus cisplatin in patients with completely resected non-small-cell lung cancer with quality of life as the primary objective. *Interact Cardiovasc Thorac Surg*. 2015;20(6):783-90.

Forde PM, Spicer J, Lu S, et al. Neoadjuvant nivolumab plus chemotherapy in resectable lung cancer. *N Engl J Med* 2022 Apr 11. doi: 10.1056/NEJMoa2202170.

Scagliotti GV, Pastorino U, Vansteenkiste JF, et al. Randomized phase III study of surgery alone or surgery plus preoperative cisplatin and gemcitabine in stages IB to IIIA non-small-cell lung cancer. *J Clin Oncol* 2012;30(2):172-8.

May 2024 Modified Rationale and Uses section based on updated NDFP eligibility

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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

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,

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