Regimen Monograph

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

A - Regimen Name

CISPPEME+NIVL Regimen

CISplatin-Pemetrexed-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-squamous 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 <u>nivolumab</u>

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

Small Cell Lung Cancer)

back to top

Davis Davissas

nivolumab¹ 4.5 mg /kg IV (max 360 mg) Day 1

pemetrexed 500 mg /m² IV Day 1

CISplatin 75 mg /m² IV over 2 hours; 30 Day 1

minutes after the end

of Pemetrexed

back to top

C - Cycle Frequency

REPEAT EVERY 21 DAYS

For 3 cycles unless disease progression or unacceptable toxicity occurs

back to top

¹Dosing based on NDFP funding criteria

D - Premedication and Supportive Measures

Antiemetic Regimen: High

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:

Pemetrexed:

- Vitamin B12 1000mcg IM every 9 weeks, Folic acid 0.4 1 mg PO daily (both starting ≥ 1 week prior to pemetrexed administration continue throughout and 3 weeks after last dose of Pemetrexed).
- Dexamethasone 4mg PO BID for 3 days starting day before chemotherapy suggested for rash prophylaxis.
- Note: NSAIDs should be held for 2-5 days prior and 2 days after pemetrexed (refer to pemetrexed monograph)

Cisplatin:

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

back to top

J - Administrative Information

Approximate Patient Visit 4-5 hours

Pharmacy Workload (average time per visit) 50.035 minutes

Nursing Workload (average time per visit) 46.667 minutes

back to top

K - References

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.

Gauvain C, Crequit P, Rousseau-Bussac G, et al. Adjuvant chemotherapy of non-small cell lung cancer: Tolerance of combined cisplatin-pemetrexed therapy. Rev Mal Respir 2014;31(9):817-21.

Kreuter M, Vansteenkiste J, Fischer JR, et al. Three-Year Follow-Up of a Randomized Phase II Trial on Refinement of Early-Stage NSCLC Adjuvant Chemotherapy with Cisplatin and Pemetrexed versus Cisplatin and Vinorelbine (the TREAT Study). J Thorac Oncol 2016;11(1):85-93.

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

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.

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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.

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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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back to top