Regimen Monograph

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

A - Regimen Name

CISPPACL+CEMI Regimen

Cisplatin-Paclitaxel-Cemiplimab

Disease Site Lung

Non-Small Cell

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 in patients with locally advanced* or metastatic non-small cell lung cancer (NSCLC)

*not suitable for curative surgery or definitive chemoradiation

(Refer to the NDFP eligibility form for detailed funding criteria.)

Supplementary

<u>cemiplimab</u>

Public Funding New Drug Funding Program (Cemiplimab - In Combination with

Chemotherapy for First-Line Treatment of Advanced Non-Small Cell Lung

Cancer) (NDFP Website)

back to top

B - Drug Regimen			
<u>PACLitaxel</u>	200 mg /m²	IV	Day 1
<u>CISplatin</u>	75 mg /m²	IV	Day 1
<u>cemiplimab</u> ¹	350 mg	IV	Day 1

¹Administer the chemotherapy drugs first, followed by cemiplimab.

back to top

C - Cycle Frequency

REPEAT EVERY 3 WEEKS

For a total of 4-6 cycles*, unless disease progression or unacceptable toxicity

After completion of CISPPACL+CEMI, continue with maintenance cemiplimab (regimen code: CEMI(MNT)).

If chemotherapy is discontinued due to toxicity, may continue with cemiplimab maintenance (regimen code: CEMI(MNT)).

back to top

^{*4} cycles of chemotherapy were given in the EMPOWER-Lung 3 study.

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 <u>hepatitis B virus screening and management</u> guideline.

Pre-medications (prophylaxis for infusion reaction):

Paclitaxel*:

- Dexamethasone 20 mg PO 12-and 6-hours OR Dexamethasone 20 mg IV 30 minutes preinfusion[†]
- Diphenhydramine 25-50 mg IV/PO 30-60 minutes pre-infusion
- Ranitidine 50 mg IV OR Famotidine 20 mg IV 30-60 minutes pre-infusion

Cemiplimab:

- Routine pre-medication is not recommended. No premedication was given for the first dose of cemiplimab during clinical trials.
- May consider premedication in patients who experienced a grade 1-2 infusion reaction. (Migden et al)

Other Supportive Care:

Cisplatin:

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

back to top

Consider **discontinuing** pre-medications for paclitaxel if there was no IR in the first 2 doses.

[†] Oral and IV dexamethasone are both effective at reducing overall IR rates. Some evidence suggests that oral dexamethasone may be more effective for reducing severe reactions; however, adverse effects and compliance remain a concern.

J - Administrative Information

Approximate Patient Visit 7 to 8 hours

Pharmacy Workload (average time per visit) 51.424 minutes

Nursing Workload (average time per visit) 59.167 minutes

back to top

K - References

CADTH Reimbursement Recommendation: Cemiplimab (Libtayo). Canadian Journal of Health Technologies. May 2024.

Cemiplimab drug monograph. Ontario Health (Cancer Care Ontario).

Cisplatin drug monograph. Ontario Health (Cancer Care Ontario).

Gogishvili M, Melkadze T, Makharadze T, et al. Cemiplimab plus chemotherapy versus chemotherapy alone in non-small cell lung cancer: a randomized, controlled, double-blind phase 3 trial. Nat Med 2022 Nov;28(11):2374-80.

Makharadze T, Gogishvili M, Melkadze T, et al. Cemiplimab plus chemotherapy versus chemotherapy alone in advanced NSCLC: 2-year follow-up from the phase 3 EMPOWER-Lung 3 Part 2 Trial. J Thorac Oncol 2023 Jun;18(6):755-68.

Paclitaxel drug monograph. Ontario Health (Cancer Care Ontario).

May 2025 Updated Rationale and Uses, Supplementary Drug Funding, and Cycle Frequency sections

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