Regimen Monograph

A - Regimen Name

PEME+CEMI(MNT) Regimen

Pemetrexed-Cemiplimab (Maintenance)

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

Maintenance treatment in patients who received platinum-pemetrexed chemotherapy and cemiplimab for locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC)

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

Supplementary Public Funding	**cemiplimab** New Drug Funding Program (Cemiplimab - In Combination with Chemotherapy for First-Line Treatment of Advanced Non-Small Cell Lung Cancer) (NDFP Website)

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B - Drug Regimen

pemetrexed	500 mg /m²	IV	Day 1
cemiplimab[1]	350 mg	IV	Day 1

[1]Administer the chemotherapy drug first, followed by cemiplimab.

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C - Cycle Frequency

REPEAT EVERY 3 WEEKS

Until disease progression or unacceptable toxicity occurs

(For up to a maximum of 2 years (36 cycles) for cemiplimab, including doses given with chemotherapy)

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

Refer to NDFP form for funding criteria for retreatment.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low

Also refer to CCO Antiemetic Recommendations.

Cemiplimab pre-medications (prophylaxis for infusion reaction):

- 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:

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)

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J - Administrative Information

Approximate Patient Visit	1.5 hours
Pharmacy Workload (average time per visit)	30.024 minutes
Nursing Workload (average time per visit)	47.50 minutes

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K - References

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

Cemiplimab 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.

Migden MR, Khushalani K, Chang ALS, et al. Cemiplimab in locally advanced cutaneous squamous cell carcinoma: results from an open-label, phase 2, single-arm trial. Lancet Oncol. 2020 Feb;21(2):294-305.

Migden MR, Rischin D, Schmults CD, et al. PD-1 blockade with cemiplimab in advanced cutaneous squamous-cell carcinoma. N Engl J Med 2018;379:341-51.

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

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

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M - Disclaimer

Regimen Abstracts

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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, 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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