Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Dose Modifications | Adverse Effects | Interactions | Drug Administration and Special Precautions | Recommended Clinical Monitoring | Administrative Information | References | Other Notes | Disclaimer

A - Regimen Name

CEMI Regimen

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.

Rationale and Uses
First-line treatment in patients with locally advanced or metastatic non–small cell lung cancer (NSCLC) expressing PD-L1 and not amenable to curative therapy

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

Supplementary Public Funding
cemiplimab
New Drug Funding Program (Cemiplimab - Previously Untreated Locally Advanced or Metastatic Non-Small Cell Lung Cancer) (NDFP Website)

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B - Drug Regimen

cemiplimab	350 mg	IV	Day 1

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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 (i.e. 36 cycles)

Refer to NDFP form for funding criteria for retreatment.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

- 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.

Premedication (prophylaxis for infusion reactions):

- 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) Refer to Management of Infusion-related Reactions table.

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated.

Dosage with toxicity

Dose reductions are not recommended for cemiplimab. Doses may be delayed or discontinued based on toxicity.

Healthcare professionals should also consult the most recent cemiplimab product monograph for additional information.

Summary of Principles of Management of Immune-related Adverse Effects (irAEs):

- Immune-related adverse effects (irAEs) are different in their presentation, onset and duration compared to conventional chemotherapy. Patient and provider education is essential.
- Initial irAEs presentation can occur months after completion of treatment and affect multiple organs.
- Dose escalation or reduction is not recommended.
- If no other cause can be identified (such as infection), any new symptom should be considered immune-related and prompt treatment initiated.
- Organ-specific system-based toxicity management is recommended.

Refer to CCO's Immune Checkpoint Inhibitor Toxicity Management Guideline for detailed descriptions of Immune-related toxicities and their management.

Management of Infusion-related Reactions:

Grade	Management	Re-challenge*
1	• Stop or slow the infusion rate (e.g. 50%) • Manage the symptoms	Consider premedication (at least 30 min prior to infusion) with: • Diphenhydramine 50mg (or equivalent) and/or acetaminophen 325 mg to 1000 mg
2	• Stop or slow the infusion rate (e.g. 50%) • Manage the symptoms	Consider premedication (at least 30 min prior to infusion) with: • Diphenhydramine 50mg (or equivalent) and/or acetaminophen 325 mg to 1000 mg • Corticosteroids (e.g. hydrocortisone 25 mg or equivalent) as necessary
3 or 4	• Stop treatment • Aggressively manage symptoms	Permanently discontinue (do not re-challenge)

*Based on Migden et al.

Hepatic Impairment

No formal studies in patients with hepatic impairment have been conducted.

Based on population pharmacokinetic analysis:

Hepatic Impairment	Cemiplimab Dose
Mild (bilirubin ≤ ULN and AST > ULN or bilirubin >1 to 1.5 x ULN and any AST) OR Moderate (bilirubin >1.5 to 3 x ULN and any AST)	No dosage adjustment is required
Severe (bilirubin >3 x ULN and any AST)	No data

Refer to CCO's Immune Checkpoint Inhibitor Toxicity Management Guideline for management of immune-related hepatic toxicities.

Renal Impairment

No formal studies in patients with renal impairment have been conducted.

Based on population pharmacokinetic analysis:

Creatinine Clearance (mL/min)	Cemiplimab Dose
≥ 15	No dose adjustment
< 15	No data

Refer to CCO's Immune Checkpoint Inhibitor Toxicity Management Guideline for management of immune-related renal toxicities.

Dosage in the Elderly

No dose adjustment required. No overall differences in efficacy were observed between patients ≥ 65 years of age and younger patients. Trends towards a higher frequency of serious adverse events and discontinuations were observed in patients 65 years and older compared to younger patients.

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F - Adverse Effects

Refer to cemiplimab drug monograph(s) for additional details of adverse effects.

Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Diarrhea (may be severe; colitis)	• Fatigue • Nausea, Vomiting • Constipation • Rash, pruritus (may be severe) • Cough • Anorexia, weight loss • Headache	• Myelosuppression (including anemia) • Immune thrombocytopenic purpura • Hypo / hyperthyroidism • Type 1 diabetes mellitus • Hypersensitivity; IRRs • Adrenal insufficiency • Meningitis, encephalitis • Hypophysitis • Hepatitis • Sjogren's syndrome, myasthenia gravis, Guillain-Barre syndrome • Myocarditis • Mucositis • Nephritis • Pneumonitis • Vasculitis • Solid organ transplant rejection • Hemophagocytic lymphohistiocytosis • Myositis • Uveitis

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G - Interactions

Refer to cemiplimab drug monograph(s) for additional details.

- No drug interaction studies have been conducted.
- Use of systemic corticosteroids or immunosuppressants should be avoided prior to starting cemiplimab because of potential interference with efficacy. They can be used to treat immune-mediated reactions after starting the drug.

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H - Drug Administration and Special Precautions

Refer to cemiplimab drug monograph(s) for additional details.

Administration

- Undiluted solution should be clear to slightly opalescent, colourless to pale yellow; discard if cloudy, discoloured or contains extraneous particulate matter other than trace amounts of translucent-to-white particles.
- Dilute in 0.9% Normal Saline or 5% Dextrose to a final concentration between 1 to 20mg/mL. Mix by gentle inversion; do not shake.
- Infuse over 30 minutes using a sterile, 0.2 to 5 micron in-line or add-on filter.
- Do not co-administer with other drugs through the same infusion line.
- Store vials at 2-8 °C; do not freeze. Protect from light.

Contraindications

- Patients who have a hypersensitivity to this drug or any of its components

Warning/Precautions

- Cemiplimab may cause serious immune-related reactions affecting multiple organ systems. Use with caution and monitor closely in patients with pre-existing conditions such as colitis, hepatic or renal impairment, respiratory or endocrine disorders, such as hypo or hyperthyroidism or diabetes mellitus.
- Patients experiencing fatigue should exercise caution when driving or operating machinery.

Pregnancy/Lactation

- This regimen is not recommended for use in pregnancy. Adequate contraception should be used by patients and their partners while on treatment and after the last treatment dose. Recommended methods and duration of contraception may differ depending on the treatment. Refer to the drug monograph(s) for more information.
- Breastfeeding is not recommended during treatment and after the last treatment dose. Refer to the drug monograph(s) for recommendations after the last treatment dose (if available).
- Fertility effects: Unknown

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I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Refer to the hepatitis B virus screening and management guideline for monitoring during and after treatment.

Recommended Clinical Monitoring

- CBC; Baseline and as clinically indicated
- Liver function tests; Baseline, before each dose and as clinically indicated; frequent with severe toxicity
- Renal function tests; Baseline, before each dose and as clinically indicated; frequent with severe toxicity
- Blood glucose; Baseline, before each dose and as clinically indicated; frequent with severe toxicity
- Thyroid function tests; Baseline, before each dose and as clinically indicated
- Clinical toxicity assessment for infusion-related reactions, immune-related reactions, including GI, endocrine, skin, neurologic, cardiac, respiratory, ocular, and musculoskeletal effects; At each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

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J - Administrative Information

Approximate Patient Visit	1 hour
Pharmacy Workload (average time per visit)	19.175 minutes
Nursing Workload (average time per visit)	42.5 minutes

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K - References

CADTH Reimbursement Recommendation: Cemiplimab (Libtayo). Canadian Journal of Health Technologies. June 2022.

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

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.

Sezer A, Kilickap S, Gümüş M, et al. Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomised, controlled trial. Lancet. 2021 Feb 13;397(10274):592-604

May 2025 new ST-QBP regimen

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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.

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 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.

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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