Ontario Santé Health Ontario | eClaims Demandes de remboursement en ligne

Eligibility Form

Cemiplimab - In Combination with Chemotherapy for First-Line Treatment of Advanced Non-Small Cell Lung Cancer

(This form should be completed before the first dose is dispensed.)

1. Patient Profile

* Surname: .....

* Given Name: .....

* OHIN: ..... * Chart Number: .....

* Postal Code: .....

* Height (cm): ..... * Weight (kg): .....

* BSA (m^2): ..... * Gender: ○ Male ○ Female ○ Other

* Date of Birth: ....
Day Month Year

* Site:

* Attending Physician (MRP- Most Responsible Physician): .....

Requested Prior Approval ☐ Yes * Patient on Clinical Trial ○ Yes ○ No

Other (specify): .....

Specify Arm:

○ Standard of care arm ○ Experimental arm

○ Blinded / Unknown

Prior Approval Request

* Select the appropriate prior approval scenario:

- ○ 1-Unknown primary (submit pathology report and clinic note)
- ○ 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below)
- ○ 3-Regimen modification - schedule (complete questions a and b)
- ○ 4-Regimen modification - drug substitutions (complete questions a and c)
- ○ 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f)
- ○ 6-Maintenance therapy delay (submit clinic note)
- ○ 7-Prior systemic therapy clinical trials (complete question g)
- ○ 8-Modification due to supply interruption/drug shortage
- ○ Other (specify)

.....

All relevant supporting documentation must be submitted at the time of prior approval. Documentation may include a pathology report, clinic note, and/or CT scans.

a. Co-morbidities / toxicity / justification:

.....

b. Intended regimen schedule: .....

c. Intended regimen: .....

d. Drug(s) to be held: .....

e. Rationale for holding drug(s): .....

f. Intention to introduce drug at a later date? ☐ Yes

g. Prior clinical trial identifier (e.g., NCT ID, trial name) and treatment description (e.g., arm, drug/regimen): .....

h. Anticipated date of first treatment: ....
Day Month Year

i. Additional comments:

2. Eligibility Criteria

Cemiplimab will be used in combination with platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced (not suitable for curative surgery or definitive chemoradiation), or metastatic non-small cell lung cancer (NSCLC). ☐ Yes

Patients must have:

- Stage IIIB – IV NSCLC
- Good performance status

Patients must not have:

- EGFR, ALK, or ROS1 tumour aberrations
- Active and/or untreated central nervous system (CNS) metastases
- Prior systemic treatment in the advanced setting

3. Baseline Information

a. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2

b. Disease stage ○ 3B ○ 3C ○ 4

c. Tumour histologic type ○ Squamous ○ Non-squamous ○ Not otherwise specified (NOS)

d. Is the patient transitioning from a private payer or compassionate program? ○ Yes ○ No

e. If yes, please indicate the funding source ○ Private payer ○ Manufacturer patient support program

f. If yes, how many doses of cemiplimab did the patient receive prior to the transition?

○ N/A	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
○ 7	○ 8	○ 9	○ 10	○ 11	○ 12	○ 13
○ 14	○ 15	○ 16	○ 17	○ 18	○ 19	○ 20
○ 21	○ 22	○ 23	○ 24	○ 25	○ 26	○ 27
○ 28	○ 29	○ 30	○ 31	○ 32	○ 33	○ 34
○ 35						

g. If yes, please indicate the date of the last administered dose. Day Month Year

4. Funded Dose

Cemiplimab 350 mg given intravenously (IV) every 3 weeks.

Treatment should continue until disease progression or unacceptable toxicity up to a maximum of 2 years' worth (i.e., 36 doses), whichever comes first.

Cemiplimab must be given in combination with platinum-based chemotherapy for the first 4-6 cycles, followed by cemiplimab (with pemetrexed for non-squamous NSCLC) for the maintenance phase.

[ST-QBP regimen code(s): CISPPACL+CEMI, CRBPPACL+CEMI, CISPPEME+CEMI, CRBPPEME+CEMI, PEME+CEMI(MNT), CEMI(MNT).

5. Notes

1. At least 1 cycle of platinum-based chemotherapy must be given concurrently with cemiplimab.

2. Ontario Health (Cancer Care Ontario) will fund one line of anti-PD1/PD-L1 therapy for advanced non-small cell lung cancer. Patients who were treated with (neo)adjuvant anti-PD1/PD-L1 therapy in the curative setting must have a disease-free interval of 6 months or greater from the last treatment dose in order to be considered for funding under this policy.

3. Patients who stop treatment due to toxicity prior to completion of the two years of therapy may restart treatment provided the toxicity has resolved.

4. Patients who complete 2 years' worth of treatment without disease progression may receive up to one additional 1 year's worth of treatment with cemiplimab (i.e., 17 doses) with or without chemotherapy, at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment and provided that no other systemic treatment is given in between. Claims should be submitted under the same form used for the initial course of treatment, and a treatment level prior approval is not required unless there is clinical uncertainty.

6. FAQs

1. **My patient is currently receiving cemiplimab through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding through the New Drug Funding Program (NDFP)?**

   Provided the eligibility criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for continued coverage through the NDFP.

2. **What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?**

   If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

   Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:
   - A clinic note and imaging (if applicable) from treatment initiation, and
   - The most recent clinic note and imaging (if applicable).

   Please note: Patients who meet the NDFP eligibility criteria and are enrolled in the manufacturer's patient support program (PSP) are eligible to receive continued drug supply through the PSP until September 2, 2025, inclusive.

   After this date, patients who met the NDFP eligibility criteria at the point of treatment initiation are eligible to transition to NDFP funding for the remainder of their treatment course. Although sites may enroll their patient onto this policy at any time beforehand, any treatment claims submitted to eClaims that were given on or before the PSP transition date will be denied.

   The NDFP will fund a total duration of 2 years' worth (or equivalent), regardless of funding source.

3. **My patient is intolerant to one (or both) of the chemotherapy agents. Can I continue therapy with the remaining agent(s)?**

   Patients who are intolerant to either one or both chemotherapy agents may continue therapy with the other agent with cemiplimab until disease progression or unacceptable toxicity. At least one cycle of platinum-based chemotherapy must be given concurrently with cemiplimab.

Supporting Documents

None required at time of enrolment.

In the event of an audit or upon request, the following should be available to document eligibility:
- Clinic notes outlining patient and treatment history/response.
- Pathology report(s) demonstrating no EGFR, ALK, or ROS1 aberrations.
- CT scans demonstrating no disease progression.
- For instances where there is pseudoprogression:
  - o Clinic note documenting the assessment and decision to continue, AND
  - o Confirmatory scan conducted preferably at 6 to 8 weeks but no later than 12 weeks after the initial disease progression to confirm the absence of true progression.

Signature of Attending Physician (MRP-Most Responsible Physician): .....

Day Month Year

Form 1086