Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Cemiplimab - Metastatic or Locally Advanced Cutaneous Squamous Cell Carcinoma

(This form must 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
- ○ 9-Supplemental doses requested
- ○ 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

The patient must meet the following criteria:

- Cemiplimab is used for patients with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) who are not candidates for curative surgery or curative radiation. ☐ Yes
- Treatment should be for previously treated (prior radiation and/or surgery) or treatment naive patients who are not amenable to curative surgery or curative radiation with good performance status.

3. Baseline Information

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

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

c. If yes to b, was the patient on an every 3 week dosing schedule? ○ Yes ○ No

d. If yes to c, how many cycles did the patient have prior to transitioning to public funding?

○ 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

e. If no to c, how many cycles did the patient have prior to transitioning to public funding?

○ 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 ○ 36
○ 37 ○ 38 ○ 39 ○ 40 ○ 41 ○ 42 ○ 43 ○ 44 ○ 45
○ 46 ○ 47

4. Funded Dose

Cemiplimab 350 mg as a fixed dose intravenously (IV) every 3 weeks.

Alternatively, a weight-based dose of 3 mg/kg IV every 2 weeks for patients with low body weight (i.e., a body mass index (BMI) of < 18.5 kg/m^2) may be considered.

Treatment with cemiplimab should continue up to 96 weeks or until symptomatic disease progression or unacceptable toxicity, whichever occurs first.

ST-QBP regimen code: CEMI

5. Notes

1. Patients may be retreated with cemiplimab provided they did not experience disease progression while being treated with cemiplimab, and are otherwise eligible for this therapy. Claims for retreatment should be submitted under the same enrolment form used for initial treatment. Retreatment may be funded for up to 96 weeks of therapy.
2. Patients with CSCC who have previously received anti-PD-1 or anti-PD-L1 therapy will not be eligible for funding under this policy.
3. Cemiplimab will not be eligible for funding under this policy if used in a neoadjuvant or adjuvant setting.

6. FAQs

i. **My patient is currently receiving cemiplimab for metastatic or locally advanced CSCC through non-publicly funded means. Can my patient be transitioned over to receive funding through the New Drug Funding Program (NDFP)?**

Provided the funding 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 of cemiplimab through NDFP. Funding is for up to a total of 96 weeks of cemiplimab, regardless of funding source. Please submit as a prior approval request including the most recent clinic note (outlining the response to therapy, if able to assess).

ii. **My patient is currently receiving systemic chemotherapy for their metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) and I wish to switch them to cemiplimab. Is this eligible for funding through NDFP?**

Patients currently on systemic chemotherapy may switch from chemotherapy to cemiplimab provided all other funding criteria are met. If choosing to switch, please submit as a prior approval request including the most recent clinic note (outlining the response to current therapy, if able to assess). Use of cemiplimab after chemotherapy will also be funded only if chemotherapy was initiated prior to the public funding of cemiplimab.

7. Supporting Documents

None required at the time of enrolment.

In the event of an audit, the following should be available to document eligibility:

- Clinic notes indicating treatment history and confirming that the patient is not a candidate for curative surgery or curative radiation.
- Pathology report confirming invasive cutaneous squamous cell carcinoma.

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

....
Day Month Year

Form 856