Ontario Health | Santé Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

Cemiplimab - Locally Advanced Basal Cell Carcinoma

(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

Specify Trial:
○ Clinical Trial 1 ○ Clinical Trial 2
○ Clinical Trial 3 ○ Other

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 for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) whose disease has been previously treated with a hedgehog pathway inhibitor (HHI). Patients must have a good performance status. ☐ Yes

Patients must not have any of the following:

- Prior treatment with PD-1 or PD-L1 pathway inhibitors
- Untreated brain metastasis that are considered active
- Active autoimmune disease requiring treatment
- Active infection requiring treatment
- Prior treatment with idelalisib

3. Baseline Information

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

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

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

d. 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

e. Please select the reason that the patient is unlikely to benefit from HHI therapy:

○ Not better than stable disease after 9 months of HHI
○ Prior disease progression on HHI therapy
○ Intolerance to HHI therapy

f. If the patient is intolerant to HHI therapy, please specify the toxicity:

○ Any grade 3 or 4 toxicity deemed related to HHI therapy
○ Grade 2 myalgia, dysgeusia, anorexia, nausea, or diarrhea in patients with at least 3 months exposure to HHI therapy

4. Funded Dose

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

Treatment should continue until evidence of symptomatic disease progression or unacceptable toxicity up to a maximum of 93 weeks (31 doses) , whichever comes first.

[ST-QBP regimen code: CEMI]

5. Notes

1. Patients who complete the initial 93 weeks of treatment with cemiplimab may be retreated with an additional 48 weeks of cemiplimab (350 mg every 3 weeks for 16 doses) if disease progression occurred off treatment and no intervening systemic anticancer therapy was given.

   Claims for retreatment should be submitted under the same form used for the initial treatment.

2. Patients with metastatic BCC are not eligible for cemiplimab.

3. Patients with locally advanced BCC whose disease is amenable to curative surgery or curative radiation are not eligible for cemiplimab.

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 treatment duration of 93 weeks for initial treatment, regardless of funding source.

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:

- Pathology report and/or imaging confirming diagnosis of locally advanced basal cell carcinoma.
- Clinic notes outlining patient and treatment history/response.
- CT scans demonstrating no disease progression.
- For instances where there is pseudoprogression:
    - Clinic note documenting the assessment and decision to continue, AND
    - 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 1084