Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Avelumab – Metastatic Merkel 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
- ○ Other (specify)

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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 one of the following criteria:

- ○ Avelumab is used for the treatment of previously treated adult patients with metastatic Merkel cell carcinoma who have good performance status and have had prior cytotoxic chemotherapy.
- ○ Avelumab is used for the treatment of adult patients with metastatic Merkel cell carcinoma who have good performance status and are ineligible for treatment with cytotoxic chemotherapy (e.g., contraindications for treatment with cytotoxic chemotherapy).

3. Baseline Information

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

b. Please select the number of prior systemic treatments for metastatic disease
- ○ 0 ○ 1 ○ 2 or more

c. Extent of distant metastatic disease
- ○ Distant skin, distant subcutaneous tissue, or distant lymph node(s) (pM1a)
- ○ Lung (pM1b)
- ○ All other distant (visceral) sites (pM1c)

4. Funded Dose

Avelumab 10 mg/kg given as an intravenous infusion every 2 weeks (ST-QBP regimen code: AVEL).

Treatment should continue until confirmed disease progression or unacceptable toxicity. For patients who achieve a complete response (CR), treatment should continue for a maximum of 12 months after confirmation of CR.

5. Notes

1. Avelumab funding is for single agent use only.
2. Patients who have a confirmed CR and relapse after stopping treatment are allowed one re-initiation of treatment if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same form used for initial treatment.

6. Supporting Documents

Initial enrolment:

- For patients with a contraindication to treatment with cytotoxic chemotherapy, a clinic note describing the nature of the contraindication needs to be uploaded to eClaims.

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

- CT scans every 3 to 6 months, along with clinic notes indicating no disease progression.
- In instances where there is pseudoprogression,
    - a clinic note documenting the assessment and decision to continue, AND
    - a 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.

7. FAQs

i. **My patient is currently receiving avelumab through private 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 avelumab through NDFP.

ii. **My patient has relapsed disease after achieving an initial complete response (CR). Is avelumab retreatment a publicly funded option?**

Patients who achieve a confirmed CR and relapse after stopping treatment are eligible for one re-initiation of treatment. This is provided the patient did not experience any toxicity that led to treatment discontinuation of the initial avelumab therapy. Retreatment may be funded until disease progression.

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

....
Day Month Year