Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Avelumab - Maintenance Treatment for Unresectable, Locally Advanced or Metastatic Urothelial 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

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

Avelumab is used for the first-line maintenance treatment of patients with histologically confirmed, unresectable, locally advanced or metastatic urothelial carcinoma whose disease has not progressed with first-line platinum-based induction chemotherapy. ☐ Yes

Treatment should be for patients with good performance status.

3. Baseline Information

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

b. Number of first-line chemotherapy cycles given ○ Less than 4 ○ 4 to 6

c. Response to first-line induction chemotherapy
○ Complete response
○ Partial response
○ Stable disease

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

4. Funded Dose

Avelumab 10 mg/kg intravenously (IV), up to a maximum of 800 mg per dose, once every two weeks.

Patients may continue to receive avelumab until confirmed disease progression or unacceptable toxicity, whichever comes first.

[ST-QBP regimen code: AVEL(MNT)]

5. Notes

1. First-line chemotherapy should be platinum-based, and patients must have received 4 to 6 cycles of treatment with chemotherapy unless fewer cycles were necessary due to a documented intolerance. Patients must not have experienced disease progression (i.e., they must have had an ongoing complete response, partial response, or stable disease) prior to initiation of avelumab maintenance.

2. Patients will not be eligible for avelumab maintenance:
    - if they have received adjuvant platinum-based chemotherapy and have disease progression within 12 months since completion of adjuvant systemic therapy. These patients may be eligible for pembrolizumab if all other eligibility criteria are met OR
    - If they have received adjuvant nivolumab and have disease progression within 6 months since completion of adjuvant systemic therapy. These patients may be eligible for enfortumab vedotin if all other eligibility criteria are met.

3. Patients who have received prior PD-1 or PD-L1 inhibitors in the advanced setting are not eligible for avelumab maintenance.

4. Patients who are not able to tolerate platinum-based chemotherapy and receive non-platinum chemotherapy may be considered for funding under this policy provided all other eligibility criteria are met, and the patient has received a minimum of 12 weeks (4 to 6 cycles) of treatment with no evidence of progressive disease on or after treatment. Requests for patients who received alternative non-platinum chemotherapy should be submitted as prior approval requests.

5. For patients who require a treatment interruption of avelumab maintenance therapy, a restart of avelumab will only be considered if the disease is still in remission.

6. FAQs

i. **My patient is currently receiving avelumab as maintenance therapy through non-publicly funded means for unresectable, locally advanced or metastatic urothelial carcinoma. 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. **Of note, patients enrolled in the manufacturer's Patient Support Program (PSP) will continue to receive treatment through the PSP until June 14, 2022. As of June 15, 2022, patients on the PSP can transition over to NDFP.** Please submit as a prior approval request including the most recent clinic note documenting remission status and response to front-line chemotherapy, no earlier than June 1, 2022.

Please note that the NDFP funded dose is 10 mg/kg, up to a maximum of 800 mg per dose.

ii. **My patient is being treated with non-platinum-based chemotherapy regimen and I would like to initiate maintenance avelumab. Is this eligible for funding through NDFP?**

Provided all other funding criteria are met, patients who use alternative non-platinum chemotherapy (e.g., gemcitabine plus paclitaxel) due to intolerance or contraindications may be eligible for maintenance avelumab, provided that patients have received a minimum of 12 weeks (4 to 6 cycles) of treatment and all other funding criteria are met. Sites should submit these requests as a prior approval (along with the most recent clinic note documenting the response to front-line chemotherapy).

Supporting Documents

None required at the time of enrolment.

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

- Clinic note indicating the patient’s clinical and treatment history, including response to first-line induction chemotherapy.
- Pathology report specifying a predominantly transitional cell histology.

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

....
Day Month Year

Form 1013