Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Tebentafusp (Outpatient) - Unresectable or Metastatic Uveal Melanoma

(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)

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

Tebentafusp is used for the first-line treatment of human leukocyte antigen (HLA)-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. ☐ Yes

Patients must have:

- A good performance status; AND
- Clinically stable central nervous system disease or no brain metastases.

3. Baseline Information

a. Does this patient have an enrolment for the inpatient version of this policy? ○ Yes ○ No

b. ECOG performance status at the time of enrolment: ○ 0 ○ 1 ○ 2

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

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

4. Funded Dose

Cycle 1 :
Tebentafusp 20 mcg intravenously (IV) on day 1, followed by 30 mcg IV on day 8, followed by 68 mcg IV on day 15.

Cycle 2 and onwards:
Tebentafusp 68 mcg IV on days 1, 8, and 15.

1 cycle = every 21 days

Treatment should continue until loss of clinical benefit or unacceptable toxicity, whichever comes first.

[ST-QBP regimen code(s): TEBE]

5. Notes

1. Enrolment in this policy is for funding of tebentafusp doses administered in the outpatient setting only. For funding of doses administered in the inpatient setting, a separate enrolment form must be submitted. See the policy '*Tebentafusp (Inpatient) - Unresectable or Metastatic Uveal Melanoma*'.

   Please ensure all claims are submitted through eClaims under the appropriate enrolment forms for inpatient and outpatient use.

2. Tebentafusp will be reimbursed on a per vial basis.

3. Patients may continue tebentafusp beyond initial radiographic progression as long as the patient continues to derive clinical benefit and there is no clear evidence of significant disease progression (e.g., decline in performance status, increased pain, rising lactate dehydrogenase, and worsening radiographic progression).

4. For patients at risk of adverse events, such as cytokine release syndrome, that require inpatient administration and monitoring of tebentafusp (e.g., the first 3 to 4 infusions) treatments should only be delivered in specialized cancer centres with experience in managing uveal melanoma. Once the patient can receive tebentafusp safely, subsequent infusions can be administered at other cancer centres or hospitals provided the treatment continues to be monitored by clinicians with experience in treating uveal melanoma.

6. FAQs

1. **My patient is currently receiving tebentafusp through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding for tebentafusp under 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 of tebentafusp through the NDFP.

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

   If the patient meets all 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 from treatment initiation, and
   - The most recent clinic note and imaging (if applicable).

   Please note: Patients who meet the eligibility criteria and are enrolled in the manufacturer's Patient Support Program (PSP) will continue to receive PSP-supplied drug through the PSP until **April 22, 2024 inclusive**.

   Although sites may enroll their patients 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.

3. **How will treatment claims be managed in eClaims?**

   Only outpatient treatment claims should be submitted under this policy.

   Inpatient administered doses must be submitted under the policy '*Tebentafusp (Inpatient) - Unresectable or Metastatic Uveal Melanoma*'.

4. **My patient is currently receiving first-line treatment for uveal melanoma. Can my patient be switched to tebentafusp?**

   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 funding of tebentafusp under this policy. Please submit a prior approval request including: a clinic note from the initiation of therapy, a recent clinic note discussing treatment response, and imaging (if applicable).

5. **My patient is currently receiving a second or later line of treatment for unresectable or metastatic uveal melanoma. Can my patient be switched to tebentafusp?**

   On a time-limited basis, your patient may be eligible for funding of tebentafusp under this policy provided the other eligibility criteria are met. Please submit a prior approval request including a recent clinic note outlining treatment history and imaging (if applicable).

7. 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:

- Report demonstrating positive HLA-A*02:01 genotype;
- Clinic note(s) outlining patient and treatment history;
- Imaging demonstrating metastatic or unresectable disease;
- Documentation of continued clinical benefit assessed through clinic visits, laboratory results, and imaging.

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

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Day Month Year

Form 1040