Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Enfortumab Vedotin - Previously Treated Advanced or Metastatic Urothelial Cancer

(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

Enfortumab vedotin is used for the treatment of adult patients with locally advanced unresectable or metastatic urothelial cancer (mUC) who have previously received platinum-containing chemotherapy and a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor therapy and have a good performance status. ☐ Yes

3. Baseline Information

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

b. The patient has stable brain metastases
○ Yes
○ N/A: The patient does not have brain metastases

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

d. If yes, please indicate the funding source
○ Private Payer
○ Manufacturer patient support program

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

4. Funded Dose

Enfortumab vedotin 1.25 mg/kg (maximum single dose of 125 mg) given intravenously (IV) on days 1, 8, and 15 of each 28-day cycle until disease progression or unacceptable toxicity, whichever comes first.

[ST-QBP regimen code: ENFO]

5. Notes

1. Enfortumab vedotin funding is for single agent use only.

2. Treatment with enfortumab vedotin should not be initiated in patients with pre-existing grade 2 or higher neuropathy or ongoing clinically significant toxicity from previous treatment, active central nervous system (CNS) metastases, uncontrolled diabetes, or active keratitis or corneal ulcerations.

6. FAQs

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

   Patients who meet the eligibility criteria may be transitioned to NDFP funding through a regular eClaims enrolment. If there is clinical uncertainty regarding eligibility, these requests may be submitted as a prior approval including a clinic note from the time of initiation as well as the most recent clinic note outlining the response to treatment (if able to assess).

   Of note, patients enrolled in the manufacturer's Patient Support Program (PSP) will continue to receive treatment through the PSP until May 27, 2023, inclusive. While these patients may enroll before May 28, 2023, please be aware any treatments submitted to eClaims that were given on or before May 27, 2023, will be denied.

ii. **My patient with mUC could not receive platinum-based chemotherapy and was previously treated with an alternative chemotherapy regimen followed by a PD-L1 inhibitor. Would my patient be eligible for enfortumab vedotin?**

   Provided all other eligibility criteria are met, patients with contraindications to platinum-based chemotherapy who have received alternative chemotherapy may be eligible for enfortumab vedotin through the NDFP. Sites should submit these requests as a prior approval request in eClaims including a clinic note(s) outlining the patient's treatment history and contraindication(s) to platinum-based chemotherapy.

iii. **My patient is currently receiving chemotherapy after prior treatment with platinum-containing chemotherapy and a PD-L1 inhibitor. Can they switch to enfortumab vedotin?**

   The decision to switch therapies should be based on a discussion between the patient and physician. Provided all other eligibility criteria are met and there is no evidence of disease progression, the patient may be switched to enfortumab vedotin. Sites should submit these requests as a prior approval request in eClaims including a clinic note(s) outlining the patient's treatment history and response to treatment (if able to assess).

iv. **My patient received platinum-based chemotherapy and experienced disease progression but had a contraindication to immunotherapy. Would my patient be eligible for enfortumab vedotin?**

   Provided all other eligibility criteria are met, requests for patients with documented contraindications to immunotherapy (i.e., PD-1 or PD-L1 inhibitor) may be considered. Sites should submit these requests as a prior approval request in eClaims including a clinic note(s) outlining the patient's treatment history and contraindication(s) to immunotherapy.

v. **My patient completed avelumab maintenance therapy and subsequently relapsed. Can they receive enfortumab vedotin?**

   Provided all other eligibility criteria are met, patients may be eligible for enfortumab vedotin through the NDFP.

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(s) documenting treatment history and response to prior therapies.

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

....
Day Month Year

Form 1011