Ontario Health | Santé Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

Enfortumab Vedotin with Pembrolizumab - Previously Untreated Locally Advanced Unresectable 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 and pembrolizumab are used for the treatment of adult patients with unresectable locally advanced or metastatic urothelial cancer with no prior systemic therapy.

☐ Yes

3. Baseline Information

a. ECOG Performance Status at the time of enrolment

○ 0 ○ 1 ○ 2

b. Previous treatment received

○ No prior systemic therapy in the (neo)adjuvant setting
○ Neoadjuvant platinum-containing chemotherapy
○ Adjuvant platinum-containing chemotherapy

c. Is the patient transitioning from a private pay or compassionate program?

○ Yes ○ No

d. If yes to 3c, please indicate the funding source

○ Private payer ○ Manufacturer patient support program

e. If yes to 3c, how many doses of pembrolizumab given every 3 weeks 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	○ 31	○ 32	○ 33	○ 34

f. If yes to 3c, how many doses of pembrolizumab given every 6 weeks 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			

g. If yes 3c, please indicate the date of the last administered dose of pembrolizumab.

Day ..... Month ..... Year .....

h. If yes to 3c, please indicate the date of the last administered dose of enfortumab vedotin.

Day ..... Month ..... Year .....

4. Funded Dose

Enfortumab vedotin 1.25 mg/kg (up to a maximum single dose of 125 mg), given intravenously (IV) on days 1 and 8 of each 21-day cycle until disease progression or unacceptable toxicity, whichever comes first.

Pembrolizumab 2 mg/kg (up to a maximum of 200 mg) given IV every 3 weeks, or 4 mg/kg (up to a maximum of 400 mg) given IV every 6 weeks.

Treatment with pembrolizumab should continue until disease progression or unacceptable toxicity, up to a maximum of 2 years of pembrolizumab (up to 35 doses given every 3 weeks, or 18 doses given every 6 weeks), whichever comes first. After completion of pembrolizumab, enfortumab vedotin may be continued until disease progression or unacceptable toxicity, whichever comes first.

[ST-QBP regimen code(s): ENFO+PEMB]

5. Notes

1. Completion of this form will enroll the patient for both enfortumab vedotin and pembrolizumab funding.

2. Patients who were previously treated in the (neo)adjuvant setting are eligible if they meet the following scenarios:

    - Neoadjuvant chemotherapy, but experienced recurrence more than 12 months after neoadjuvant chemotherapy was completed; OR
    - Adjuvant chemotherapy following cystectomy, but experienced recurrence more than 12 months after adjuvant chemotherapy was completed; OR
    - Adjuvant immunotherapy, but experienced recurrence more than 6 months after treatment was completed.

3. Treatment with enfortumab vedotin in combination with pembrolizumab should not be initiated in patients with:

    - Active central nervous system (CNS) metastases
    - Uncontrolled diabetes
    - Prior enfortumab vedotin or other monomethyl auristatin E (MMAE)-based antibody drug conjugates (ADCs).

4. Patients that have urothelial tumours with squamous or sarcomatoid differentiation or mixed cell types will be eligible under this policy provided all other funding criteria are met.

5. Patients who complete 2 years' worth of treatment with pembrolizumab without disease progression may receive up to an additional 1 year's worth of treatment of pembrolizumab (17 doses given every 3 weeks, or 9 doses given every 6 weeks), with or without enfortumab vedotin, at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same enrolment form used for initial treatment.

6. FAQs

1. **My patient is currently receiving enfortumab vedotin and/or pembrolizumab 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 programs (PSPs) are eligible to receive continued drug supply through the PSPs until November 25, 2025, inclusive, for pembrolizumab, and until December 7, 2025, inclusive, for enfortumab vedotin.

   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.

   Based on the recommendations from Canada's Drug Agency, Ontario Health (Cancer Care Ontario) does not reimburse hospitals for pembrolizumab given as a fixed or flat dose under this policy. Regardless of the patient's prior funding source or prior dosing, NDFP will fund the weight-based dosing as indicated in the Funded Dose section above.

   The NDFP will fund a total duration of 2 years for the initial treatment with pembrolizumab, regardless of funding source.

3. **My patient is currently receiving an alternate first-line therapy for locally advanced unresectable or metastatic urothelial cancer. Can my patient be switched to enfortumab vedotin plus pembrolizumab?**

   On a time-limited basis, your patient may be eligible for funding of enfortumab vedotin plus pembrolizumab under this policy provided they have not completed platinum-based first-line chemotherapy. Please submit a prior approval request with supporting documentation (i.e., CT scans indicating stable disease, clinic note indicating reason for switching).

4. **My patient is intolerant to one of the drugs in the regimen. Can they continue therapy with the remaining agent?**

   Patients who are intolerant to one component of the regimen may continue therapy with the remaining agent until disease progression, unacceptable toxicity, or until the maximum funded duration, whichever comes first.

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:

- Clinic notes outlining patient and treatment history/response.
- CT scans demonstrating no disease progression.
- Pathology report showing histologically documented, unresectable locally advanced or metastatic urothelial cancer.
- In instances where there is pseudoprogression, a clinic note documenting the assessment and decision to continue, and the subsequent CT scan confirming no disease progression.

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

....
Day Month Year

Form 1113