Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - Locally Advanced Unresectable or Metastatic Biliary Tract 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

Pembrolizumab is used in combination with gemcitabine-based chemotherapy for the first-line treatment of adult patients with locally advanced (not amenable to surgery) or metastatic biliary tract cancer (BTC). ☐ Yes

Patients must have:

- Unresectable or metastatic disease at initial diagnosis (or greater than 6 months after the completion of neoadjuvant therapy or curative surgery); AND
- A good performance status.

3. Baseline Information

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

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

c. If yes, please indicate the funding source. ○ Private payer ○ Manufacturer patient support program

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

e. If yes, 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, 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			

4. Funded Dose

Pembrolizumab 2 mg/kg intravenously (IV) (up to a maximum of 200 mg) every 3 weeks, or pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks, given in combination with gemcitabine-based chemotherapy.

Treatment should continue until confirmed disease progression or unacceptable toxicity up to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first.

[ST-QBP regimen code(s): CISPGEMC+PEMB, CISPGEMC(W)+PEMB, CRBPGEMC+PEMB, GEMC+PEMB(MNT), PEMB(MNT)]

5. Notes

1. Treatment with pembrolizumab (plus gemcitabine-based chemotherapy) is not to be used in patients with Ampulla of Vater (AoV) cancer.

2. Patients must receive at least 1 cycle of chemotherapy in combination with pembrolizumab.

3. Patients who complete 2 years' worth of treatment without disease progression or recurrence on pembrolizumab may receive up to an additional 1 year's worth of treatment (with or without gemcitabine-based chemotherapy for 17 cycles if given every 3 weeks or 9 cycles if given every 6 weeks) at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment.

4. Patients who experience toxicity to alternate first-line chemoimmunotherapy regimens may be funded for one switch to an alternate immunotherapy agent, provided there is no disease progression.

6. FAQs

1. **My patient is currently receiving 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 program (PSP) are eligible to receive continued drug supply through the PSP until February 15, 2025, inclusive.

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 (CDA), 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.

3. **My patient is currently on first-line chemotherapy for BTC. Can I add pembrolizumab to the regimen?**

Patients who are currently receiving first-line chemotherapy may add pembrolizumab to the regimen, provided there is no disease progression.

4. **My patient can no longer tolerate any chemotherapy. Can they continue with pembrolizumab therapy?**

All patients must receive at least 1 cycle of chemotherapy with pembrolizumab. If a patient is unable to tolerate further chemotherapy, they can continue with pembrolizumab monotherapy as per the Funded Dose section.

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.
- For instances where there is pseudoprogression:
    - o Clinic note documenting the assessment and decision to continue, AND
    - o 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.

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

....
Day Month Year

Form 1077