Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

# Durvalumab - 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

Durvalumab is used in combination with gemcitabine plus platinum-based chemotherapy for the first-line treatment of 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 adjuvant 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 pay 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

## 4. Funded Dose

Durvalumab 1500 mg* intravenously (IV) once every 3 weeks (in combination with gemcitabine plus platinum-based chemotherapy) for up to 8 cycles, followed by durvalumab 1500 mg* once every 4 weeks as monotherapy until objective disease progression or unacceptable toxicity.

*For patients weighing less than or equal to 30 kg, a weight-based durvalumab dose of 20 mg/kg is used until weight increases to greater than 30 kg.

[ST-QBP regimen code(s): One of CISPGEMC(W)+DURV, CISPGEMC+DURV, CBRPGEMC+DURV, followed by DURV(MNT) for use as maintenance]

## 5. Notes

1. Treatment with durvalumab (plus gemcitabine and platinum-based chemotherapy) is not to be used in patients with Ampulla of Vater (AoV) cancer.
2. BTC eligible subtypes are intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer.
3. Patients must receive at least 1 cycle of chemotherapy with durvalumab.
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 durvalumab through non-publicly funded means (e.g. patient support program, private insurance). Can my patient be transitioned to receive funding for durvalumab 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 durvalumab 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).

3. **If a patient is not able to tolerate cisplatin-based chemotherapy, is it reasonable to combine durvalumab with alternate chemotherapy?**

   Durvalumab is only funded if used in combination with gemcitabine plus platinum-based therapy.

4. **Can durvalumab be restarted if treatment was stopped for reasons other than disease progression?**

   Provided durvalumab was not stopped due to objective disease progression or unacceptable toxicity, the patient will continue to be eligible for durvalumab funding. If there is disease progression while on a drug holiday, durvalumab will only be funded in combination with chemotherapy.

5. **Is durvalumab eligible for funding in patients currently on, or who have just completed a first-line chemotherapy regimen?**

   On a time-limited basis, patients who are currently receiving first-line chemotherapy (gemcitabine plus platinum) with no evidence of disease progression may add durvalumab. Patients who have completed first-line chemotherapy are not eligible for the addition of durvalumab.

## 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:

- Pathology report demonstrating histologically confirmed diagnosis of BTC.
- CT scans every 9 to 12 weeks indicating no disease progression.
- Instances where there is pseudoprogression:
    - Clinic note documenting the assessment and decision to continue, AND
    - 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