Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Durvalumab in combination with Tremelimumab - Previously Untreated Unresectable or Metastatic Hepatocellular Carcinoma (HCC)

(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)

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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 tremelimumab for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC) who require systemic therapy and are no longer amenable to local therapies.

☐ Yes

Patients must have a good performance status and a Child-Pugh score of class A.

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 date of the last administered dose: _____ _____ _____
Day Month Year

4. Funded Dose

Durvalumab 1500 mg* intravenously (IV) in combination with tremelimumab 300 mg IV for cycle 1 only, followed by durvalumab 1500 mg* IV once every 28 days until loss of clinical benefit** or unacceptable toxicity, whichever comes first.

*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. A weight-based tremelimumab dose of 4 mg/kg should be used for these patients.

**In the pivotal trial, treatment was permitted beyond disease progression if the patient was clinically stable and deriving clinical benefit.

[ST-QBP regimen code(s): DURV+TREM for cycle 1, followed by DURV(MNT)]

5. Notes

1. Completion of this form will enroll the patient in both durvalumab and tremelimumab.

2. Patients with fibrolamellar HCC, sarcomatoid HCC, mixed cholangiocarcinoma and HCC, or have severe autoimmune or inflammatory disorders are not eligible for funding under this policy.

3. Durvalumab and tremelimumab is not funded if used in combination with any other systemic treatment for HCC.

4. Patients who experience unacceptable toxicity or intolerance to alternate first line therapies for HCC may be eligible to switch to durvalumab and tremelimumab provided there is no disease progression. Only one switch between atezolizumab/bevacizumab and durvalumab/tremelimumab will be considered.

6. FAQs

1. **My patient is currently receiving durvalumab and tremelimumab 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).

3. **My patient has recently started an alternate first-line therapy, but I would prefer to use durvalumab and tremelimumab. Can my patient be switched to durvalumab and tremelimumab?**

   On a time-limited basis, patients who are currently being treated with atezolizumab in combination with bevacizumab and are experiencing unacceptable toxicity or intolerance may be eligible to switch to durvalumab in combination with tremelimumab, provided there is no disease progression. Please note that only one switch between atezolizumab with bevacizumab and durvalumab with tremelimumab will be considered.

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 the patient's clinical and treatment history/response, including determination of the Child-Pugh liver function classification.
- CT scans every 9 to 12 weeks indicating no disease progression.
- For 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

Form 1048