Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Atezolizumab with Bevacizumab (Biosimilar) - Previously Untreated Unresectable or Metastatic Hepatocellular Carcinoma

(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

The patient must meet the following criteria:

Atezolizumab is used in combination with bevacizumab for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC) who require systemic therapy and have had no prior systemic treatment. ☐ Yes

Treatment should be for patients with an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 and a Child-Pugh 'A' liver function classification.

3. Baseline Information

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

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

4. Funded Dose

Atezolizumab 1200 mg intravenously (IV) and bevacizumab 15 mg/kg IV on day 1 of each 21-day cycle.

Treatment with atezolizumab and bevacizumab should be continued until loss of clinical benefit* or unacceptable toxicity, whichever comes first.

[ST-QBP regimen code: ATEZBEVA]

*In the pivotal trial, loss of clinical benefit was determined after an assessment of biochemical and radiographic data ar of clinical status (e.g., symptomatic deterioration such as pain due to disease). Treatment beyond radiographic disease progression could continue if there is observed evidence of clinical benefit, and symptoms and signs indicating unequivocal disease progression are absent.

5. Notes

1. Patients with fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC are not eligible for funding under this policy.

2. Patients who stop either atezolizumab or bevacizumab due to intolerance may continue treatment with the remaining agent in the absence of progression if the clinician determines there would be clinical benefit. Monotherapy with the remaining agent should stop if the patient develops intolerance or has progression.

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

6. FAQs

i. **My patient is currently receiving atezolizumab with bevacizumab through non-publicly funded means for HCC. Can my patient be transitioned over to receive funding through the New Drug Funding Program (NDFP)?**

Provided the funding 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 atezolizumab with bevacizumab through NDFP. Please submit a a prior approval request including the most recent clinic note (and response to therapy, if able to assess).

ii. **My patient has initiated alternative first-line systemic treatment, and has not progressed. Is my patient eligible for a switch to atezolizumab with bevacizumab?**

Yes, provided all other funding criteria are met, NDFP can accommodate a switch to atezolizumab with bevacizumab fo patients currently on first-line systemic therapy, such as sorafenib or lenvatinib, and who have not progressed. Please submit as a prior approval request including the most recent clinic note (and response to therapy, if able to assess), along with the rationale for the switch.

iii. **What publicly funded treatment options are available for my patient after disease progression on first-line atezolizumab with bevacizumab?**

Patients may be eligible for second line lenvatinib or sorafenib (if intolerant of lenvatinib). Please refer to the Ministry of Health's Exceptional Access Program for more details.

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 indicating the patient's clinical and treatment history, pathology report confirming HCC, and determination of the Child-Pugh liver function classification.

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

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Day Month Year