Ontario Health | Santé Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

Nivolumab plus Ipilimumab - Previously Untreated Unresectable or Advanced 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)

.....

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

Combination nivolumab and ipilimumab will be used for the treatment of adult patients with previously untreated unresectable or advanced hepatocellular carcinoma (HCC). ☐ Yes

Patients must have:

- A Child-Pugh score class A; 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, how many doses of ipilimumab did the patient receive prior to the transition?
○ 1 ○ 2 ○ 3 ○ 4

e. If yes, how many doses of combination nivolumab (dosed every 3 weeks) did the patient receive?
○ 1 ○ 2 ○ 3 ○ 4

f. If yes, how many doses of nivolumab maintenance (dosed every 2 weeks) did the patient receive?
○ 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 ○ 35
○ 36 ○ 37 ○ 38 ○ 39 ○ 40 ○ 41 ○ 42 ○ 43 ○ 44
○ 45

g. If yes, how many doses of nivolumab maintenance (dosed every 4 weeks) did the patient receive?
○ N/A ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8
○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ 15 ○ 16 ○ 17
○ 18 ○ 19 ○ 20 ○ 21 ○ 22

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

4. Funded Dose

Ipilimumab 3 mg/kg intravenously (IV) every 3 weeks in combination with nivolumab 1 mg/kg IV every 3 weeks for a total of 4 doses of combination therapy, followed by:

- Nivolumab 3 mg/kg (up to 240 mg) IV every 2 weeks OR
- Nivolumab 6 mg/kg (up to 480 mg) IV every 4 weeks as maintenance.

Treatment should continue until disease progression or unacceptable toxicity up to a maximum of 12 weeks of ipilimumab and 2 years of nivolumab, whichever comes first.

[ST-QBP regimen code(s): NIVL+IPIL, NIVL (MNT)]

5. Notes

1. Patients who had a partial resection, but failure to surgically remove all the HCC, may be eligible provided they meet all of the eligibility criteria and the clinician deems treatment to be appropriate.

2. Patients who have residual disease and can no longer be treated with locoregional therapy may be eligible provided they meet all of the eligibility criteria and the clinician deems treatment to be appropriate.

3. Patients who have only received locoregional therapy may be eligible for funding provided the patient meets all of the eligibility criteria outlined in this policy.

4. Patients will be ineligible for funding if they are diagnosed with fibrolamellar hepatocellular carcinoma, sarcomatoid hepatocellular carcinoma, or mixed cholangiocarcinoma and hepatocellular carcinoma.

5. A minimum of one cycle must be given with nivolumab in combination with ipilimumab. After one cycle, patients may discontinue ipilimumab and continue with nivolumab monotherapy if the patient is experiencing unacceptable toxicity.

6. Patients who complete two years' worth of ipilimumab plus nivolumab without disease progression may receive up to one additional year's worth of retreatment at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment, **more than 6 months has elapsed since stopping the initial treatment**, and provided that no other systemic treatment is given in between.

   Retreatment should include combination nivolumab and ipilimumab for 12 weeks, followed by nivolumab maintenance.

   Claims should be submitted under the same form used for the initial course of treatment.

6. FAQs

1. **My patient is currently receiving ipilimumab and/or nivolumab 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 from treatment initiation (including Child Pugh score), and
   - Imaging 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) may transition to NDFP funding as of the effective funding date noted in the PDRP memo.

   Based on the recommendations from Canada's Drug Agency, Ontario Health (Cancer Care Ontario) does not reimburse hospitals for ipilimumab and nivolumab 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 12 weeks for ipilimumab and 2 years for nivolumab as part of the initial course of treatment, regardless of funding source.

3. **My patient is currently being treated with an alternate first-line regimen (e.g., combination atezolizumab and bevacizumab, combination durvalumab and tremelimumab). Can my patient switch to combination nivolumab plus ipilimumab?**

   On a time-limited basis, patients who experience toxicity or intolerance to their current regimen will be eligible to switch to combination nivolumab plus ipilimumab provided they have not experienced disease progression on an alternate first-line regimen. Please submit a prior approval request noting the reason for the switch as well as upload the most recent clinic note and imaging.

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:
  - 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 1128