Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Nivolumab plus Ipilimumab - Advanced Melanoma (Unresectable or Metastatic Melanoma)

(This form must 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:

- Combination nivolumab plus ipilimumab is used for the treatment of unresectable or metastatic melanoma regardless of BRAF status, who are treatment naïve or may have received prior treatment with BRAF-targeted therapy, with ECOG performance status of 0 or 1 and with stable brain metastases (if present). ☐ Yes

3. Baseline Information

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

b. Disease Status ○ Unresectable Stage III ○ Stage IV

c. BRAF V600 mutation status ○ Positive ○ Negative ○ Unknown

d. If BRAF positive, the patient has been treated with a BRAF and/or MEK inhibitor. ○ Yes ○ No

e. The patient has stable brain metastases ○ Yes ○ Not applicable, the patient does not have brain metastases

f. The patient is transitioning from the MELODY program ○ Yes ○ No

4. Funded Dose

Nivolumab 1mg/kg and ipilimumab 3mg/kg every three weeks for up to four doses (ST-QBP regimen code: NIVL+IPIL), followed by

- Nivolumab maintenance at 3mg/kg up to a maximum of 240mg every two weeks
  or
- Nivolumab maintenance at 6mg/kg up to a maximum of 480mg every four weeks (ST-QBP regimen code: NIVL(MNT)).

Patients enrolling in this policy must be able to initiate treatment with nivolumab and ipilimumab at the same time.

Treatment with combination nivolumab plus ipilimumab (followed by nivolumab maintenance) should be continued until unacceptable toxicity or confirmed disease progression.

5. Notes

1. Patients with BRAF mutation may be initiated on BRAF targeted therapy or immunotherapy. Upon disease progression, the patient may be switched to the other treatment modality as a subsequent line of therapy.

2. For patients who stop nivolumab maintenance without disease progression, continuation of maintenance nivolumab will be funded provided that no other treatment is given in between.

3. Completion of this form will automatically enroll the patient for both nivolumab and ipilimumab.

4. Combination nivolumab plus ipilimumab is not funded for patients who have confirmed disease progression while receiving a prior anti-PD-1 inhibitor.

6. FAQs

i. **My patient is currently receiving combination nivolumab plus ipilimumab through private means. 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 combination nivolumab plus ipilimumab through NDFP.

ii. **My patient has started first line nivolumab (or pembrolizumab) but I would prefer to switch my patient to combination nivolumab plus ipilimumab. Will CCO fund the switch?**

   For a 3 month time period (i.e., until July 4, 2019), patients currently on an anti-PD-1 monotherapy as their initial immunotherapy in the metastatic setting are eligible to switch to combination nivolumab plus ipilimumab provided there has been no disease progression.

iii. **My patient's disease has progressed on first line pembrolizumab (or nivolumab). Is my patient eligible for combination nivolumab plus ipilimumab funding?**

   Patients whose disease is progressing or has progressed on anti PD-1 monotherapy are not eligible for combination nivolumab plus ipilimumab.

iv. **My patient's disease has progressed on first line nivolumab (or pembrolizumab). Will CCO fund subsequent ipilimumab?**

   For patients treated with anti-PD-1 monotherapy (instead of combination nivolumab plus ipilimumab) in the metastatic setting, ipilimumab monotherapy will be funded as a subsequent line of therapy provided that funding criteria are met.

v. **My patient had to take a treatment break from combination nivolumab plus ipilimumab. Is retreatment funded?**

   Retreatment with combination nivolumab plus ipilimumab is not funded if the patient completed a course of induction. However, your patient may be eligible for continuation of nivolumab maintenance provided that no other treatment is given in between.

   Subsequent pembrolizumab after combination nivolumab plus ipilimumab is not funded.

vi. **I would like to start my patient on nivolumab and add ipilimumab at a later date. How do I enroll my patient?**

   Patients enrolling in this policy must be able to initiate treatment with both nivolumab and ipilimumab at the same time.

   If your patient is not able to tolerate combination nivolumab plus ipilimumab at the time of treatment initiation, single agent nivolumab or pembrolizumab remains as an option for initial immunotherapy, with single agent ipilimumab as a subsequent line of therapy.

7. Supporting Documents

If the patient is switching from single agent nivolumab or pembrolizumab to combination nivolumab plus ipilimumab, the following must be uploaded upon enrolment:

- Clinic notes confirming that the patient's disease has not yet progressed and rationale for the switch.
- Recent CT scan if available.

In the event of an audit, CCO may request the following:

- CT scans every 3 to 6 months, along with clinic notes confirming no disease progression.
- In instances where there is pseudoprogression, a clinic note documenting the assessment and decision to continue, and the subsequent CT scan confirming no disease progression.

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

....
Day Month Year