Ontario Health | Santé Ontario

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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)

**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 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<br>○ 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<br>○ Not applicable, the patient does not have brain metastases |

## 4. Funded Dose

Nivolumab 1 mg/kg and ipilimumab 3 mg/kg every three weeks for up to four doses, 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.

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.

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

## 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 may be funded for patients who have confirmed disease progression while receiving a prior anti-PD-1 or anti-PD-L1 inhibitor in the adjuvant setting or experience disease progression within 6 months of completing adjuvant anti-PD-1 or anti-PD-L1 therapy, provided that the patient meets all of the eligibility criteria.

## 6. FAQs

1. **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.

2. **My patient's disease has progressed on alternative first line immunotherapy pembrolizumab or nivolumab in the advanced setting. Is my patient eligible for combination nivolumab plus ipilimumab funding?**

   Patients whose disease has progressed on alternative first line anti PD-1/anti-PD-L1 monotherapy in the advanced setting are not eligible for combination nivolumab plus ipilimumab..

3. **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.

4. **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

None required at the time of enrolment.

In the event of an audit or upon request, the following should be available to document eligibility:

- Clinic note(s) outlining patient and treatment history/response (if applicable).
- 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