Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Nivolumab - 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
- ○ 9-Supplemental doses requested
- ○ 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:

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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:

- Nivolumab is used as a treatment for patients with unresectable or metastatic melanoma, regardless of BRAF status, who are previously untreated or may have received prior treatment with BRAF targeted therapy, with good performance status and who have 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 3
○ Stage 4

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

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

e. The patient has received the following prior to nivolumab (check all that apply) ○ BRAF inhibitor ○ MEK inhibitor ○ No prior treatment

4. Funded Dose

- Nivolumab 3 mg/kg IV, up to a maximum dose of 240 mg, every 2 weeks as an intravenous infusion, or nivolumab 6 mg/kg IV, up to a maximum dose of 480 mg, every 4 weeks as an intravenous infusion.

5. Notes

1. The patient is no longer eligible for nivolumab once there is confirmed disease progression.
2. Nivolumab is not funded for patients who have confirmed disease progression while receiving a prior anti-PD-1 inhibitor.
3. 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.
4. Nivolumab funding is for single agent use only.
5. For patients completing or stopping single agent nivolumab without disease progression, resumption of treatment will be funded provided no other treatment is given in between.
6. 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.

6. FAQs

1. **My patient is currently receiving nivolumab through private means. Can my patient be transitioned over to receive funding through the New Drug Funding Program (NDFP)?**

   Provided the funding rules 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 nivolumab through the New Drug Funding Program.

2. **My patient has previously been treated with ipilimumab. Is my patient eligible to receive nivolumab?**

   pCODR did not recommend funding nivolumab for the treatment of patients with unresectable or metastatic melanoma who have previously received treatment with ipilimumab.

   However, patients who have received ipilimumab before the effective funding date of pembrolizumab (i.e., received at least one treatment of ipilimumab prior to June 2, 2016) are eligible to receive pembrolizumab upon disease progression.

   Please refer to the document: "Cancer Drug Funding in Ontario" for further information on the drug funding decision-making process.

3. **My patient's disease has progressed on first line nivolumab. Will CCO fund subsequent ipilimumab?**

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

4. **My patient is currently receiving nivolumab on an every 2 week schedule. Can my patient be transitioned over to the every 4 week schedule?**

   The decision to switch should be based on a discussion between the clinician and patient. Switches between schedules (from every 2 weeks to every 4 weeks or vice versa) will be eligible for continued funding provided the patient's disease has not progressed.

5. **What is the rationale for having a maximum dose for the every 2 week schedule?**

   Exposure-response relationships for efficacy and clinical safety have shown that the benefit-risk profile is comparable between weight-based dosing and the 240 mg flat dose. Weight-based dosing, up to a maximum dose, will be applied across all nivolumab policies and is in alignment with other Canadian jurisdictions who have implemented nivolumab.

6. **My patient is currently on the every 2 week schedule at a dose greater than 240 mg. Will this dose continue to be eligible for funding?**

   On a time-limited basis (until November 2, 2018), CCO will allow funding for doses greater than 240 mg for patients who initiated treatment with the 3 mg/kg every 2 week schedule prior to September 7, 2018. This time-limited funding allows clinicians an opportunity to inform patients of the revised dosing schedule, and to update their computerized prescriber order entry (CPOE) systems accordingly. Starting November 3, 2018, reimbursement will be capped at 240 mg for the every 2 week schedule. Patients who switch to the 6 mg/kg every 4 week schedule are required to adhere to the maximum dose of 480 mg as of the effective funding date.

7. **My patient is currently on a 'treatment break' and requires resumption of their nivolumab therapy. If their original dose exceeded 240 mg, are clinicians required to adopt the maximum dose cap?**

   Upon resumption of therapy, patients on a 'treatment break' will be required to adhere to the funded dose for any dose(s) given after November 2, 2018 (e.g., 3 mg/kg, up to 240 mg, every 2 weeks or 6 mg/kg, up to 480 mg, every 4 weeks).

7. Supporting Documents

None required for this policy.

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

- CT scans every 3 to 6 months, along with clinic notes indicating no disease progression.
- In instances where there is pseudoprogression,
    - a clinic note **documenting** the assessment and decision to continue, AND
    - a 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): .....

03	10	2019
Day	Month	Year