Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Nivolumab - Adjuvant Treatment for Completely Resected Stage III or IV 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 patien 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 no
- ○ 7-Prior systemic therapy clinical trials (comple question g)
- ○ 8-Modification due to supply interruption/drug shortage
- ○ 9-Supplemental doses requested
- ○ 10-COVID-19 pandemic: switch from adjuvant dabrafenib-trametinib
- ○ 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:

- Nivolumab is used for the adjuvant treatment of adult patients with completely resected stage IIIA (with node metastases >1mm), IIIB, IIIC, IIID or stage IV melanoma and; ☐ Yes
- Disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed.

3. Baseline Information

a. ECOG performance status at the time of enrolment ○ 0 ○ 1 ○ 2

b. Disease stage ○ IIIA (node metastasis >1mm) ○ IIIB ○ IIIC ○ IIID ○ IV

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

d. The patient has received prior adjuvant treatment for their primary disease ○ Yes ○ No

If yes: how many treatment months?

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12

e. The patient had a complete lymph node dissection ○ Yes ○ No

4. Funded Dose

Nivolumab 3 mg/kg intravenously (IV) once every 2 weeks up to a maximum dose of 240 mg until disease progression or a maximum of one year of equivalent therapy, whichever comes first.

OR

Nivolumab 6 mg/kg intravenously (IV) once every 4 weeks up to a maximum dose of 480 mg until disease progression or a maximum of one year of equivalent therapy, whichever comes first.

ST-QBP regimen code: NIVL

5. Notes

1. Staging is based on the 8th edition of the American Joint Committee on Cancer (AJCC) melanoma staging system.
2. Patients with stage IIIA melanoma must have node metastases >1mm to be eligible for funding.
3. In-transit, satellite or distant metastases must be completely resected.
4. Patients with BRAF mutated melanoma who initiated treatment with adjuvant immunotherapy or adjuvant dabrafenib and trametinib may switch once between adjuvant therapies within 3 months of initiation of therapy. Funded therapy will be limited to a total of 12 months of adjuvant treatment, regardless of funding source.
5. Patients who initiated adjuvant therapy with interferon may switch once to adjuvant immunotherapy or adjuvant dabrafenib and trametinib, provided all eligibility criteria are met.
6. Patients with ocular melanoma will not be eligible for adjuvant nivolumab.
7. Nivolumab is funded for single agent use only.
8. Patients who have confirmed disease progression on adjuvant nivolumab will not be eligible for anti-PD-1/anti-PD-L1 immunotherapy (e.g. pembrolizumab or nivolumab) in the metastatic setting.
9. Patients whose disease recurs at least 6 months after their last dose of adjuvant pembrolizumab for resected stage IIB-IIC disease may be eligible for adjuvant nivolumab or pembrolizumab for resected stage III-IV disease provided all other eligibility criteria are met.
10. Patients whose disease relapses at least 6 months after completing adjuvant nivolumab may be eligible for combination ipilimumab & nivolumab in the metastatic setting. If the patient is unfit for combination immunotherapy, they may be eligible for single agent immunotherapy.

6. FAQs

i. ***My patient is currently receiving nivolumab through non-publicly funded 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 nivolumab through NDFP. Funding is for a total of 12 treatment months, regardless of funding source. Please note that the NDFP funded dose is 3 mg/kg up to a maximum of 240 mg (every two weeks) or 6 mg/kg up to a maximum of 480 mg (every four weeks).

ii. ***My patient's disease progressed while on adjuvant nivolumab. Is my patient eligible for immunotherapy in the metastatic setting?***

Patients who have confirmed disease progression on adjuvant nivolumab will not be eligible for any anti-PD-1 policies (single agent nivolumab, pembrolizumab or combination nivolumab plus ipilimumab) in the metastatic setting. However, your patient may be eligible for single agent ipilimumab.

iii. ***My patient's disease has relapsed after completion of adjuvant nivolumab. Is my patient eligible for combination ipilimumab & nivolumab?***

Patients whose disease relapses at least 6 months after completing adjuvant nivolumab may be eligible for combination ipilimumab & nivolumab in the metastatic setting. If the patient is unfit for combination immunotherapy, they may be eligible for single agent immunotherapy.

iv. ***My BRAF mutated patient has started adjuvant treatment with immunotherapy or targeted therapy and wishes to switch treatment modalities. What treatment options are publicly funded?***

BRAF positive patients who switch within the first 3 months of initiating treatment may switch once from adjuvant immunotherapy (pembrolizumab or nivolumab) to adjuvant dabrafenib & trametinib or from adjuvant dabrafenib & trametinib to adjuvant immunotherapy (pembrolizumab or nivolumab). Funded therapy will be limited to a total of 12 months of adjuvant treatment, regardless of funding source.

v. ***My patient needs to take a treatment break from nivolumab. Will resumption of treatment be funded?***

For patients who stop nivolumab without disease progression, continuation of nivolumab (to complete the total of 1 year of adjuvant treatment) will be funded provided that no other treatment is given in between.

7. Supporting Documents

None required for this policy.

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

- Clinic note and/or surgical pathology report to confirm staging.

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

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Day Month Year