Ontario Health | Santé Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

Nivolumab plus Ipilimumab - (Neo)adjuvant Resectable Macroscopic Stage III Melanoma

(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 with ipilimumab will be used for the treatment of patients with macroscopic resectable stage III melanoma in the neoadjuvant setting. For BRAF wild-type patients who did not achieve a major pathological response*, single agent nivolumab will be used in the adjuvant setting afterwards. ☐ Yes

Patients must:

- be at least 16 years of age or older; AND
- have confirmed resectable stage III melanoma of cutaneous or unknown primary origin with 1 or more macroscopic lymph node metastases that can be biopsied, or any number of resectable in-transit metastases); AND
- have a good performance status.

*A major pathological response is defined as less than or equal to 10% residual visible tumour.

3. Baseline Information

a. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2

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

c. Is the patient transitioning from a private payer? ○ Yes ○ No

d. If yes, how many neoadjuvant doses of nivolumab with ipilimumab did the patient receive prior to the transition?
○ N/A ○ 1 ○ 2

e. If yes, how many adjuvant doses of nivolumab did the patient receive prior to the transition? ○ N/A ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10

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

4. Funded Dose

In the neoadjuvant setting:
Nivolumab 240 mg in combination with ipilimumab 80 mg intravenously (IV) every 3 weeks for a total of 2 cycles.

In the adjuvant setting (for patients who are BRAF wild type and did not achieve a major pathologic response*):
Nivolumab 6 mg/kg (up to a maximum of 480 mg) IV every 4 weeks until disease progression, unacceptable toxicities,or up to a maximum of 11 cycles, whichever comes first.

[ST-QBP regimen code(s): NIVL+IPIL for the neoadjuvant portion followed by NIVL for the adjuvant portion (if applicable)]

5. Notes

1. Per the NADINA trial, macroscopic lymph nodes were defined as:

    - A palpable node that is pathologically confirmed as melanoma; or
    - A nonpalpable but enlarged lymph node according to RECIST 1.1 (at least 15 mm in short axis) that is pathologically confirmed as melanoma; or
    - A PET scan positive lymph node of any size that is pathologically confirmed as melanoma.

2. Completion of this form will automatically enroll the patient for both neoadjuvant nivolumab with ipilimumab as well as adjuvant nivolumab for eligible patients.

3. Patients with mucosal melanoma are eligible for funding under this policy.

4. Patients with uveal melanoma are ineligible for funding under this policy.

6. FAQs

1. **My patient is currently receiving neoadjuvant nivolumab with ipilimumab or adjuvant nivolumab through non-publicly funded means (e.g., 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 and imaging (if applicable) from treatment initiation, and
   - The most recent clinic note and imaging (if applicable).
   - Pathology report confirming BRAF status.
   - Pathology report(s) describing pathologic response post-neoadjuvant therapy

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 notes outlining patient and treatment history/response.
- CT scans demonstrating no disease progression.
- Pathology report confirming BRAF status.
- Pathology report(s) describing pathologic response post-neoadjuvant therapy.

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

....
Day Month Year

Form 1096