Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Nivolumab plus Ipilimumab - Advanced Malignant Pleural Mesothelioma

(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

Specify Trial: ○ OTHER

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 adult patients with unresectable malignant pleural mesothelioma (MPM) who have not received prior systemic therapy for MPM, and who have good performance status. ☐ Yes

3. Baseline Information

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

b. Tumour histologic subtype ○ Epithelioid ○ Non-epithelioid

c. Has the patient received prior systemic therapy for MPM other than nivolumab plus ipilimumab? ○ Yes ○ No

d. Is the patient transitioning from a private pay or compassionate program? ○ Yes ○ No

e. If yes to 3d, was the patient on an every 3 week dosing schedule of nivolumab? ○ Yes ○ No

f. If yes to 3e, how many treatments of every 3 week nivolumab did the patient have prior to transitioning to public funding?

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9
○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ 15 ○ 16 ○ 17 ○ 18
○ 19 ○ 20 ○ 21 ○ 22 ○ 23 ○ 24 ○ 25 ○ 26 ○ 27
○ 28 ○ 29 ○ 30 ○ 31 ○ 32 ○ 33 ○ 34

g. If no to 3e, how many treatments of every 2 week nivolumab did the patient have prior to transitioning to public funding?

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9
○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ 15 ○ 16 ○ 17 ○ 18
○ 19 ○ 20 ○ 21 ○ 22 ○ 23 ○ 24 ○ 25 ○ 26 ○ 27
○ 28 ○ 29 ○ 30 ○ 31 ○ 32 ○ 33 ○ 34 ○ 35 ○ 36
○ 37 ○ 38 ○ 39 ○ 40 ○ 41 ○ 42 ○ 43 ○ 44 ○ 45
○ 46 ○ 47 ○ 48 ○ 49 ○ 50 ○ 51

h. If yes to 3d, how many treatments of ipilimumab did the patient have prior to transitioning to public funding?

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9
○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ 15 ○ 16 ○ 17

i. Patients with mesothelioma may be eligible for coverage through the Workplace Safety and Insurance Board (WSIB) (e.g., patients who worked in a trade in Ontario involving asbestos exposure in the past). For this patient, is there an active claim with the WSIB? ○ Yes ○ No

j. If yes to 3i, ‘Your patient is not eligible for funding through the New Drug Funding Program. For patients currently receiving WSIB benefits, please contact WSIB directly to discuss any claim-related issues.’

k. If no to 3i, 'Please indicate why the patient does not have an active WSIB claim for mesothelioma: (select all that apply)'

- ☐ Patient was not exposed to asbestos while working in Ontario
- ☐ Patient did not work in an industry covered by WSIB
- ☐ Claim is pending review by WSIB
- ☐ Other: (Please specify)

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4. Funded Dose

Nivolumab 4.5 mg/kg intravenously (IV), up to a maximum dose of 360 mg, once every 3 weeks plus ipilimumab 1 mg/kg IV once every 6 weeks.

Treatment with combination nivolumab plus ipilimumab should continue until confirmed disease progression or unacceptable toxicity to a maximum of two years, whichever comes first.

[ST-QBP regimen code: NIVL+IPIL]

5. Notes

1. Patients who stop ipilimumab, in the absence of disease progression, may continue treatment with nivolumab monotherapy. Nivolumab monotherapy should stop if the patient experiences serious adverse effects, has disease progression, or after completion of two years of therapy.
2. Completion of this form will automatically enroll the patient for both nivolumab and ipilimumab.
3. Patients who complete 2 years’ worth of nivolumab plus ipilimumab without disease progression may receive an additional 1 years’ worth of nivolumab plus ipilimumab at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment and no other systemic treatment is given in between. Claims should be submitted under the same enrolment form used for initial treatment.
4. Patients receiving funding for systemic treatment from WSIB are not eligible for funding through the New Drug Funding Program (NDFP). For patients currently receiving WSIB benefits, please contact WSIB directly to discuss any claim-related issues.

6. FAQs

i. **My patient is currently receiving nivolumab plus ipilimumab through non-publicly funded means for unresectable MPM. Can my patient be transitioned over to receive funding through 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 plus ipilimumab through NDFP. Please submit as a prior approval request including the most recent clinic note documenting the response to treatment, if able to assess, and number of cycles of nivolumab plus ipilimumab received to date.

At the NDFP funded dose of nivolumab 4.5 mg/kg (up to a maximum of 360 mg per dose) every 3 weeks, funding (in combination with ipilimumab 1 mg/kg every 6 weeks) is for a total of 2 years' worth of treatment for the initial course, regardless of funding source.

ii. **My patient has initiated alternative first-line systemic treatment, and has not progressed. Is my patient eligible for a switch to nivolumab plus ipilimumab?**

Yes, provided all other funding criteria are met, NDFP can accommodate a switch to nivolumab plus ipilimumab for patients currently on first-line systemic treatment and who have not progressed. Please submit as a prior approval request including the most recent clinic note (and response to therapy, if able to assess).

iii. **What publicly funded treatment options are available for my patient after disease progression on first-line nivolumab plus ipilimumab?**

After disease progression on nivolumab plus ipilimumab, standard chemotherapy options (e.g., platinum/pemetrexed then gemcitabine or vinorelbine) remain available.

iv. **As a result of an occupational exposure to asbestos, my patient was subsequently diagnosed with mesotheiloma. Are they eligible for coverage of nivolumab plus ipilimumab through NDFP?**

If your patient has an accepted claim with WSIB for mesothelioma, then medications for mesothelioma including nivolumab plus ipilimumab are covered by the WSIB, and not NDFP. Please refer to the WSIB Operational Policy Manual for more information (https://www.wsib.ca/en/operational-policy-manual/long-term-exposures/occupational-diseases). If your patient has not filed a claim with WSIB and they had occupational exposure to asbestos in Ontario, please contact WSIB and discuss filing a claim. If the claim has been denied, you can submit as a prior approval request in eClaims for funding consideration of nivolumab plus ipilimumab through NDFP.

Supporting Documents

None required at the time of enrolment.

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

- Clinic note(s) documenting treatment history.
- 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.
- Pathology report confirming MPM including tumour histologic subtype.
- Imaging/investigation results confirming unresectable disease.

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

....
Day Month Year