

Pembrolizumab - (Neo)adjuvant Treatment for Completely Resectable Stage III or IV 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 (m²):
- * 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:
- | | |
|---|---|
| <input type="radio"/> 1-Unknown primary (submit pathology report and clinic note) | <input type="radio"/> 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below) |
| <input type="radio"/> 3-Regimen modification - schedule (complete questions a and b) | <input type="radio"/> 4-Regimen modification - drug substitutions (complete questions a and c) |
| <input type="radio"/> 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f) | <input type="radio"/> 6-Maintenance therapy delay (submit clinic note) |
| <input type="radio"/> 7-Prior systemic therapy clinical trials (complete question g) | <input type="radio"/> 8-Modification due to supply interruption/drug shortage |
| <input type="radio"/> 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 ☐ Yes
at a later date?

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:

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2. Eligibility Criteria

- Pembrolizumab is used for the neoadjuvant treatment of adult patients with clinically detectable and measurable stage IIIB, IIIC, IIID, or resectable stage IV cutaneous melanoma followed by adjuvant pembrolizumab; OR ☐ Yes
- Pembrolizumab is used for the adjuvant treatment of adult patients with completely resected stage IIIA (with node metastases >1mm), IIIB, IIIC, IIID or stage IV cutaneous melanoma. The patient's 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. Please specify the planned treatment intent. ☐ Neoadjuvant then adjuvant ☐ Adjuvant

4. Funded Dose

Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 3 weeks; or

Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks.

Treatment should be continued until disease progression or unacceptable toxicity up to a maximum of 12 months (or equivalent therapy*), whichever comes first.

*18 cycles if administered every 3 weeks, or 9 cycles if administered every 6 weeks.

For neoadjuvant then adjuvant use, 3 cycles of every 3-week pembrolizumab are given neoadjuvantly, followed by 15 cycles every 3 weeks in the adjuvant setting.

[ST-QBP regimen code: PEMB]

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 >1 mm to be eligible for funding of adjuvant pembrolizumab. Patients with stage IIIA disease are NOT eligible for neoadjuvant then adjuvant pembrolizumab based on the pivotal trial.
3. In-transit, satellite or distant metastases must be completely resected.
4. Patients with ocular melanoma will not be eligible for (neo)adjuvant pembrolizumab.
5. Pembrolizumab is funded for single agent use only.
6. Patients whose disease recurs at least 6 months after their last dose of adjuvant nivolumab or pembrolizumab for resected stage IIB-IIC disease may be eligible for adjuvant nivolumab or (neo)adjuvant pembrolizumab for stage III-IV completely resectable disease.

6. FAQs

1. My patient is currently receiving pembrolizumab 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 pembrolizumab through NDFP. Funding is for a total of 12 treatment months, regardless of funding source. Please note that the NDFP funded dose is 2 mg/kg up to a maximum of 200 mg per dose or 4 mg/kg up to a maximum of 400 mg per dose.

2. 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

3. My patient needs to take a treatment break from pembrolizumab. Will resumption of treatment be funded?

For patients who stop pembrolizumab without disease progression, continuation of pembrolizumab (to complete the total of 12 months of (neo)adjuvant treatment) will be funded provided that no other treatment is given in between.

4. My patient is currently receiving pembrolizumab on an every 3 week schedule. Can my patient be transitioned over to an every 6 week schedule?

The decision to switch should be based on a discussion between the clinician and patient. Switches between schedules (from every 3 weeks to every 6 weeks or vice versa) will be eligible for continued funding provided the patient's disease has not progressed. Please note that the funded duration remains the same (i.e., a maximum of 12 months or equivalent therapy).

Supporting Documents

None required.

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

- Clinic note and/or surgical pathology report to confirm staging and treatment intent.
- Surgical report confirming complete resection of disease.

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

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Day Month Year