

APPLICANT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg No:	First Names:	First Names:
Name:	Surname:	Surname:
Address:	DOB:	Address:
.....	Address:
.....
Fax Number:	Fax Number:

Pembrolizumab

Initial application — unresectable or metastatic melanoma

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV
- and
- ☐ Baseline measurement of overall tumour burden is documented clinically and radiologically
- and
- ☐ The patient has ECOG performance score of 0-2
- and
- ☐ Patient has not received funded nivolumab

or

☐ Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance

and

☐ The cancer did not progress while the patient was on nivolumab
- and
- ☐ Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses

Renewal — unresectable or metastatic melanoma, less than 24 months on treatment

Current approval Number (if known):.....

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ Patient's disease has had a complete response to treatment

or

☐ Patient's disease has had a partial response to treatment

or

☐ Patient has stable disease
- and
- ☐ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period
- and
- ☐ The treatment remains clinically appropriate and the patient is benefitting from the treatment
- or
- ☐ Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression

and

☐ Patient has signs of disease progression

and

☐ Disease has not progressed during previous treatment with pembrolizumab

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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Pembrolizumab - continued

Renewal — unresectable or metastatic melanoma, more than 24 months on treatment

Current approval Number (if known):.....

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

☐ Patient has been on treatment for more than 24 months

and

☐ Patient's disease has had a complete response to treatment

or

☐ Patient's disease has had a partial response to treatment

or

☐ Patient has stable disease

and

☐ Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period

and

☐ The treatment remains clinically appropriate and the patient is benefitting from the treatment

or

☐ Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression

and

☐ Patient has signs of disease progression

and

☐ Disease has not progressed during previous treatment with pembrolizumab

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Pembrolizumab - *continued*

Initial application — non-small cell lung cancer first-line monotherapy

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer
and ☐ Patient has not had chemotherapy for their disease in the palliative setting
and ☐ Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC
and ☐ For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain
and ☐ Pembrolizumab to be used as monotherapy
and

☐ There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 50% as determined by a validated test unless not possible to ascertain
or

☐ There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 1% as determined by a validated test unless not possible to ascertain
and ☐ Chemotherapy is determined to be not in the best interest of the patient based on clinician assessment
- and** ☐ Patient has an ECOG 0-2
and ☐ Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks
and ☐ Baseline measurement of overall tumour burden is documented clinically and radiologically

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Pembrolizumab - continued

Renewal — non-small cell lung cancer first line monotherapy

Current approval Number (if known):.....

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ Patient's disease has had a complete response to treatment
or
☐ Patient's disease has had a partial response to treatment
or
☐ Patient has stable disease

and

- ☐ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

and

- ☐ No evidence of disease progression

and

- ☐ The treatment remains clinically appropriate and patient is benefitting from treatment

and

- ☐ Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent)

and

- ☐ Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

Initial application — non-small cell lung cancer first-line combination therapy

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer
and
☐ The patient has not had chemotherapy for their disease in the palliative setting
and
☐ Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC
and
☐ For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain
and
☐ Pembrolizumab to be used in combination with platinum-based chemotherapy
and
☐ Patient has an ECOG 0-2
and
☐ Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks
and
☐ Baseline measurement of overall tumour burden is documented clinically and radiologically

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Pembrolizumab - *continued*

Renewal — non-small cell lung cancer first line combination therapy

Current approval Number (if known):.....

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ Patient's disease has had a complete response to treatment

or

☐ Patient's disease has had a partial response to treatment

or

☐ Patient has stable disease

- and ☐ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period
- and ☐ No evidence of disease progression
- and ☐ The treatment remains clinically appropriate and patient is benefitting from treatment
- and ☐ Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent)
- and ☐ Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

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