HOSPITAL MEDICINES LIST
RESTRICTIONS CHECKLIST

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab

INITIATION – unresectable or metastatic melanoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

CONTINUATION – unresectable or metastatic melanoma, less than 24 months on treatment
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

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 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 that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

CONTINUATION – unresectable or metastatic melanoma, more than 24 months on treatment
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

I confirm that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

INITIATION – non-small cell lung cancer first-line monotherapy
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

CONTINUATION – non-small cell lung cancer first-line monotherapy
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

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 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)

INITIATION – non-small cell lung cancer first-line combination therapy
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

CONTINUATION – non-small cell lung cancer first-line combination therapy
Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

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 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)

I confirm that the above details are correct:

Signed: ..... Date: .....