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: .....

Nivolumab

INITIATION
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 pembrolizumab

or

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

and

- ○ The cancer did not progress while the patient was on pembrolizumab

and

- ○ Documentation confirming that the patient has been informed and acknowledges that funded treatment with nivolumab will not be continued if their disease progresses

CONTINUATION – 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 nivolumab 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 nivolumab

I confirm that the above details are correct:

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

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: .....

Nivolumab *- continued*

CONTINUATION – 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 nivolumab 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 nivolumab

I confirm that the above details are correct:

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

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: .....

Nivolumab *- continued*

INITIATION – renal cell carcinoma, first line
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Patient is currently on treatment with nivolumab and met all remaining criteria prior to commencing treatment

or

- ○ The patient has metastatic renal cell carcinoma

and

- ○ The patient is treatment naive

and

- ○ The patient has ECOG performance status 0-2

and

- ○ The disease is predominantly of clear cell histology

and

- ○ The patient has sarcomatoid histology

or

- ○ Haemoglobin levels less than the lower limit of normal

or

- ○ Corrected serum calcium level greater than 10 mg/dL (2.5 mmol/L)

or

- ○ Neutrophils greater than the upper limit of normal

or

- ○ Platelets greater than the upper limit of normal

or

- ○ Interval of less than 1 year from original diagnosis to the start of systemic therapy

or

- ○ Karnofsky performance score of less than or equal to 70

and

- ○ Nivolumab is to be used in combination with ipilimumab for the first four treatment cycles at a maximum dose of 3 mg/kg

and

- ○ Nivolumab is to be used at a maximum maintenance dose of 240 mg every 2 weeks (or equivalent)

INITIATION – renal cell carcinoma, second line
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has metastatic renal-cell carcinoma

and

- ○ The disease is of predominant clear-cell histology

and

- ○ Patient has ECOG performance status 0-2

and

- ○ Patient has documented disease progression following one or two previous regimens of antiangiogenic therapy

and

- ○ Patient has not previously received a funded immune checkpoint inhibitor

and

- ○ Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression

I confirm that the above details are correct:

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

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: .....

Nivolumab *- continued*

CONTINUATION – renal cell carcinoma
Re-assessment required after 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

- ○ No evidence of disease progression

and

- ○ Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression

I confirm that the above details are correct:

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