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: .....

Nivolumab

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

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

and

- ○ The individual 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 individual has ECOG performance 0-2

and

- ○ The individual has not received funded pembrolizumab

or

- ○ The individual 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 individual was on pembrolizumab

and

- ○ The individual has been diagnosed in the metastatic or unresectable stage III or IV setting

or

- ○ The individual did not receive treatment in the perioperative setting with a PD-1/PD-L1 inhibitor

or

- ○ The individual received treatment in the perioperative setting with a PD-1/PD-L1 inhibitor

and

- ○ The individual did not experience disease recurrence while on treatment with that PD-1/PD-L1 inhibitor

and

- ○ The individual did not experience disease recurrence within six months of completing perioperative treatment with a PD-1/PD-L1 inhibitor

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nivolumab *- continued*

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

and

- ○ The individual's disease has had a complete response to treatment
  or
- ○ The individual's disease has had a partial response to treatment
  or
- ○ The individual has stable disease

and

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

or

- ○ The individual has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression

and

- ○ The individual has signs of disease progression

and

- ○ Disease has not progressed during previous treatment with nivolumab

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

and

- ○ The individual has been on treatment for more than 24 months

and

- ○ The individual's disease has had a complete response to treatment
  or
- ○ The individual's disease has had a partial response to treatment
  or
- ○ The individual 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

or

- ○ The individual has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression

and

- ○ The individual has signs of disease progression

and

- ○ Disease has not progressed during previous treatment with nivolumab

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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

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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: .....