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
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

INITIATION – Renal cell carcinoma
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

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

or

- ○ Patient has metastatic renal-cell carcinoma

and

- ○ The disease is of predominant clear-cell histology

and

- ○ Patient has an ECOG performance score of 0-2

and

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

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: .....

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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)

❍ Prescribed by, or recommended by any relevant practitioner, 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

❍ 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: .....