

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

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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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PATIENT:

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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

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