

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: Name:

Ward: 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: Name:

Ward: 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: Name:

Ward: 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 naïve

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: 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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