

<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT NHI:</b> .....	<b>REFERRER</b> Reg No: .....
Reg No: .....	First Names: .....	First Names: .....
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Address: .....	DOB: .....	Address: .....
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## Nivolumab

### Initial application — unresectable or metastatic melanoma

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

- ☐ 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

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Nivolumab** - continued

**Renewal — unresectable or metastatic melanoma, less than 24 months on treatment**

Current approval Number (if known):.....

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

☐ 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

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**Nivolumab** - continued

**Renewal — unresectable or metastatic melanoma, more than 24 months on treatment**

Current approval Number (if known):.....

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The individual has been on treatment for more than 24 months
and	
<input type="checkbox"/>	The individual's disease has had a complete response to treatment
or	
<input type="checkbox"/>	The individual's disease has had a partial response to treatment
or	
<input type="checkbox"/>	The individual has stable disease
and	
<input type="checkbox"/>	Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period
or	
<input type="checkbox"/>	The individual has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression
and	
<input type="checkbox"/>	The individual has signs of disease progression
and	
<input type="checkbox"/>	Disease has not progressed during previous treatment with nivolumab

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**Nivolumab** - continued

**Initial application — renal cell carcinoma, first line**

Applications from any relevant practitioner. Approvals valid for 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 as monotherapy at a maximum maintenance dose of 240 mg every 2 weeks (or equivalent)

**Initial application — Renal cell carcinoma, second line**

Applications from any relevant practitioner. Approvals valid for 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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**Nivolumab** - continued

**Renewal — Renal cell carcinoma**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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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