

**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER** Reg No: .....

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**Nivolumab**

**Initial application — stage III or IV resectable 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 is currently on treatment with nivolumab for neoadjuvant treatment of resectable stage IIIB, IIIC, IIID or IV melanoma and met all remaining criteria prior to commencing treatment
- or
- The individual has resectable stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note)

and  The individual has not received prior funded systemic treatment in the perioperative setting for their stage IIIB, IIIC, IIID or IV melanoma

and  The individual has ECOG performance score 0-2

and  Treatment must be initiated prior to complete surgical resection

and  Neoadjuvant nivolumab must be administered in combination with ipilimumab

and  Nivolumab to be administered for maximum of two cycles prior to surgical resection

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 — stage III or IV resectable melanoma**

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 received funded neoadjuvant treatment with nivolumab in combination with ipilimumab <b>and</b> <input type="checkbox"/> Adjuvant treatment with nivolumab is required <b>and</b> <input type="checkbox"/> Treatment must be initiated within 13 weeks of complete surgical resection, unless delay is necessary due to post-surgery recovery <b>and</b> <input type="checkbox"/> Nivolumab must be administered as monotherapy <b>and</b> <input type="checkbox"/> Nivolumab to be discontinued at signs of disease recurrence or at completion of 12 months total treatment duration including any systemic neoadjuvant treatment (equivalent to 11 adjuvant cycles at 480 mg every 4 weeks plus initial 2 neoadjuvant treatment cycles)
<b>or</b>
<input type="checkbox"/> The individual has received neoadjuvant treatment with nivolumab and ipilimumab <b>and</b> <input type="checkbox"/> The individual has unresectable or metastatic melanoma (excluding uveal) stage III or IV <b>and</b> <input type="checkbox"/> The individual meets initial application criteria for nivolumab for unresectable or metastatic melanoma
<b>or</b>
<input type="checkbox"/> The individual has received neoadjuvant treatment with nivolumab and ipilimumab <b>and</b> <input type="checkbox"/> The individual has received treatment with nivolumab for unresectable or metastatic melanoma <b>and</b> <input type="checkbox"/> The individual meets the renewal criteria for nivolumab for unresectable or metastatic melanoma

**Note:**

- a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition.
- b) Disease must be completely resectable and amenable to curative intent surgery, including stage IV disease.

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**Nivolumab** - *continued*

**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

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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
<b>and</b>	
<input type="checkbox"/>	The individual's disease has had a complete response to treatment
<b>or</b>	
<input type="checkbox"/>	The individual's disease has had a partial response to treatment
<b>or</b>	
<input type="checkbox"/>	The individual has stable disease
<b>and</b>	
<input type="checkbox"/>	Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period
<b>or</b>	
<input type="checkbox"/>	The individual has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression
<b>and</b>	
<input type="checkbox"/>	The individual has signs of disease progression
<b>and</b>	
<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)

- |  |
|--|
| <input type="checkbox"/> Patient's disease has had a complete response to treatment<br><b>or</b><br><input type="checkbox"/> Patient's disease has had a partial response to treatment<br><b>or</b><br><input type="checkbox"/> 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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