

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

Reg No: .....      First Names: .....      First Names: .....

Name: .....      Surname: .....      Surname: .....

Address: .....      DOB: .....      Address: .....

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Fax Number: .....      Fax Number: .....

**Nivolumab**

**Initial application**

Applications only from a medical oncologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal — less than 24 months on treatment**

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

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. 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**  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 the above details are correct and that in signing this form I understand I may be audited.**

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

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

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**Nivolumab** - *continued*

**Renewal — more than 24 months on treatment**

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

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has been on treatment for more than 24 months
<b>and</b>	
<input type="checkbox"/>	Patient's disease has had a complete response to treatment
<b>or</b>	
<input type="checkbox"/>	Patient's disease has had a partial response to treatment
<b>or</b>	
<input type="checkbox"/>	Patient 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>and</b>	
<input type="checkbox"/>	The treatment remains clinically appropriate and the patient is benefitting from the treatment
<b>or</b>	
<input type="checkbox"/>	Patient has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression
<b>and</b>	
<input type="checkbox"/>	Patient 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)

- 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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