

APPLICANT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg No:	First Names:	First Names:
Name:	Surname:	Surname:
Address:	DOB:	Address:
.....	Address:
.....
Fax Number:	Fax Number:

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)

<input type="checkbox"/>	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	
<input type="checkbox"/>	The individual has resectable stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note)
and	
<input type="checkbox"/>	The individual has not received prior funded systemic treatment in the perioperative setting for their stage IIIB, IIIC, IIID or IV melanoma
and	
<input type="checkbox"/>	The individual has ECOG performance score 0-2
and	
<input type="checkbox"/>	Treatment must be initiated prior to complete surgical resection
and	
<input type="checkbox"/>	Neoadjuvant nivolumab must be administered in combination with ipilimumab
and	
<input type="checkbox"/>	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.

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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)

The individual has received funded neoadjuvant treatment with nivolumab in combination with ipilimumab
and
 Adjuvant treatment with nivolumab is required
and
 Treatment must be initiated within 13 weeks of complete surgical resection, unless delay is necessary due to post-surgery recovery
and
 Nivolumab must be administered as monotherapy
and
 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)

or

The individual has received neoadjuvant treatment with nivolumab and ipilimumab
and
 The individual has unresectable or metastatic melanoma (excluding uveal) stage III or IV
and
 The individual meets initial application criteria for nivolumab for unresectable or metastatic melanoma

or

The individual has received neoadjuvant treatment with nivolumab and ipilimumab
and
 The individual has received treatment with nivolumab for unresectable or metastatic melanoma
and
 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
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)

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