

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)

☐ 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:

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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)

☐	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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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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