HOSPITAL MEDICINES LIST
RESTRICTIONS CHECKLIST

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nivolumab

INITIATION – stage III or IV resectable melanoma
Re-assessment required after 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

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nivolumab *- continued*

CONTINUATION – stage III or IV resectable melanoma
Re-assessment required after 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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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nivolumab *- continued*

INITIATION – unresectable or metastatic melanoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nivolumab *- continued*

CONTINUATION – unresectable or metastatic melanoma, less than 24 months on treatment
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

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 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

CONTINUATION – unresectable or metastatic melanoma, more than 24 months on treatment
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nivolumab *- continued*

INITIATION – renal cell carcinoma, first line
Re-assessment required after 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 at a maximum maintenance dose of 240 mg every 2 weeks (or equivalent)

INITIATION – renal cell carcinoma, second line
Re-assessment required after 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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Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nivolumab *- continued*

CONTINUATION – renal cell carcinoma
Re-assessment required after 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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