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: .....

Trametinib

INITIATION – stage III or IV resected melanoma - adjuvant
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

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

and

- ○ The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a)

or

- ○ The individual has received neoadjuvant treatment with a PD-1/PD-L1 inhibitor

and

- ○ Adjuvant treatment with trametinib is required

and

- ○ The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma

and

- ○ Treatment must be adjuvant to complete surgical resection

and

- ○ Treatment must be initiated within 13 weeks of surgical resection, unless delay is necessary due to post-surgery recovery (see note b)

and

- ○ The individual has a confirmed BRAF mutation

and

- ○ Trametinib must be administered in combination with dabrafenib

and

- ○ The individual has ECOG performance score 0-2

Note:

a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition

b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)

I confirm that the above details are correct:

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

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Trametinib *- continued*

CONTINUATION – stage III or IV resected melanoma - adjuvant
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

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

and

- ○ No evidence of disease recurrence

and

- ○ Trametinib must be administered in combination with dabrafenib

and

- ○ Treatment to be discontinued at signs of disease recurrence or at completion of 12 months' total treatment course, including any systemic neoadjuvant treatment

or

- ○ The individual has received adjuvant treatment with a BRAF/MEK inhibitor

and

- ○ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV

and

- ○ The individual meets initiation criteria for trametinib for unresectable or metastatic melanoma

or

- ○ The individual has received adjuvant treatment with a BRAF/MEK inhibitor

and

- ○ The individual has received a BRAF/MEK inhibitor for unresectable or metastatic melanoma

and

- ○ The individual meets continuation criteria for trametinib for unresectable or metastatic melanoma

I confirm that the above details are correct:

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

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: .....

Trametinib *- continued*

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

- ○ Prescribed by, or recommended by any relevant practitioner, 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 melanoma) stage III or IV

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

and

- ○ The individual has ECOG performance score 0-2

and

- ○ The individual has confirmed BRAF mutation

and

- ○ Trametinib must be administered in combination with dabrafenib

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 adjuvant setting with a BRAF/MEK inhibitor

or

- ○ The individual received treatment in the adjuvant setting with a BRAF/MEK inhibitor

and

- ○ The individual did not experience disease recurrence while on treatment with that BRAF/MEK inhibitor

and

- ○ The individual did not experience disease recurrence within six months of completing adjuvant treatment with a BRAF/MEK inhibitor

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

- ○ Prescribed by, or recommended by any relevant practitioner, 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 with treatment

and

- ○ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

I confirm that the above details are correct:

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