

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:

Dabrafenib

Initial application — stage III or IV resected melanoma - adjuvant
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

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 dabrafenib 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

Dabrafenib must be administered in combination with trametinib

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 the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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Dabrafenib - *continued*

Renewal — stage III or IV resected melanoma - adjuvant

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

Applications from any relevant practitioner. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

No evidence of disease recurrence
and
 Dabrafenib must be administered in combination with trametinib
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 initial application criteria for dabrafenib 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 renewal criteria for dabrafenib for unresectable or metastatic melanoma

I confirm the above details are correct and that in signing this form I understand I may be audited.

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Dabrafenib - continued

Initial application — unresectable or metastatic melanoma

Applications from any relevant practitioner. 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 score 0-2

and The individual has confirmed BRAF mutation

and Dabrafenib must be administered in combination with trametinib

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

Renewal — unresectable or metastatic melanoma

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

Applications from any relevant practitioner. 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 with treatment

and

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

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