Ministry of Health
Phone 0800 243 666

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA1657
November 2019

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

.....

.....

Fax Number: .....

PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

Address: .....

.....

.....

REFERRER Reg No: .....

First Names: .....

Surname: .....

Address: .....

.....

.....

Fax Number: .....

Pembrolizumab

INITIAL APPLICATION - unresectable or metastatic melanoma
Applications only from a medical oncologist. Approvals valid for 4 months.

Prerequisites (tick boxes where appropriate)

- ☐ Patient has metastatic or unresectable melanoma stage III or IV

and

- ☐ Patient has measurable disease as defined by the presence of at least one CT or MRI measurable lesion

and

- ☐ The patient has ECOG performance score of 0-2

and

- ☐ Patient has not received funded nivolumab

or

- ☐ Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance

and

- ☐ The cancer did not progress while the patient was on nivolumab

and

- ☐ Pembrolizumab is to be used at a maximum dose of 2 mg/kg every 3 weeks for a maximum of 12 weeks (4 cycles)

and

- ☐ Baseline measurement of overall tumour burden is documented (see Note)

and

- ☐ Documentation confirming that the patient has been informed and acknowledges that the initial funded treatment period of pembrolizumab will not be continued beyond 12 weeks (4 cycles) if their disease progresses during this time

See also: **RENEWAL** - unresectable or metastatic melanoma *p2*

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

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – Fax: 0800 100 131

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Reg No:	First Names:	First Names: .....
Name:	Surname:	Surname: .....
Address:	DOB:	Address: .....
.....	Address:	.....
.....	.....	.....
Fax Number:	.....	Fax Number: .....

Pembrolizumab *- continued*

RENEWAL - unresectable or metastatic melanoma

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

Applications only from a medical oncologist. Approvals valid for 4 months.

Prerequisites (tick boxes where appropriate)

☐ Patient's disease has had a complete response to treatment according to RECIST criteria (see Note)
or
☐ Patient's disease has had a partial response to treatment according to RECIST criteria (see Note)
or
☐ Patient has stable disease according to RECIST criteria (see Note)

and
☐ Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period
and
☐ No evidence of progressive disease according to RECIST criteria (see Note)
and
☐ The treatment remains clinically appropriate and the patient is benefitting from the treatment
and
☐ Pembrolizumab will be used at a maximum dose of 2 mg/kg every 3 weeks for a maximum of 12 weeks (4 cycles)

Note:

Disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47). Assessments of overall tumour burden and measurable disease to be undertaken on a minimum of one lesion and maximum of 5 target lesions (maximum two lesions per organ). Target lesions should be selected on the basis of their size (lesions with the longest diameter), be representative of all involved organs, and suitable for reproducible repeated measurements. Target lesion measurements should be assessed using CT or MRI imaging with the same method of assessment and the same technique used to characterise each identified and reported lesion at baseline and every 12 weeks. Response definitions as follows:

- Complete Response: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm.
- Partial Response: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
- Progressive Disease: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).
- Stable Disease: Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease.

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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