

SA2386 - Pembrolizumab

MSI-H/dMMR advanced colorectal cancer - Initial application	9
MSI-H/dMMR advanced colorectal cancer - Renewal	10
Urothelial carcinoma - Initial application	10
Urothelial carcinoma - Renewal	10
Breast cancer, advanced - Initial application	7
Breast cancer, advanced - Renewal	8
Head and neck squamous cell carcinoma - Initial application	8
Head and neck squamous cell carcinoma - Renewal	9
Non-small cell lung cancer first line combination therapy - Renewal	6
Non-small cell lung cancer first line monotherapy - Renewal	5
Non-small cell lung cancer first-line combination therapy - Initial application	5
Non-small cell lung cancer first-line monotherapy - Initial application	4
Relapsed/refractory Hodgkin lymphoma - Initial application	11
Relapsed/refractory Hodgkin lymphoma - Renewal	11
Unresectable or metastatic melanoma - Initial application	2
Unresectable or metastatic melanoma, less than 24 months on treatment - Renewal	2
Unresectable or metastatic melanoma, more than 24 months on treatment - Renewal	3

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:

Pembrolizumab

Initial application — unresectable or metastatic melanoma

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

Patient 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 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 Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses

Renewal — unresectable or metastatic melanoma, less than 24 months on treatment

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

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. 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 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

and The treatment remains clinically appropriate and the patient is benefitting from the treatment

or

Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression

and Patient has signs of disease progression

and Disease has not progressed during previous treatment with pembrolizumab

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 – email: customerservice@health.govt.nz

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:

Pembrolizumab - continued

Renewal — unresectable or metastatic melanoma, more than 24 months on treatment

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

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

Patient has been on treatment for more than 24 months

and

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

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

and

The treatment remains clinically appropriate and the patient is benefitting from the treatment

or

Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression

and

Patient has signs of disease progression

and

Disease has not progressed during previous treatment with pembrolizumab

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 – email: customerservice@health.govt.nz

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:

Pembrolizumab - continued

Initial application — non-small cell lung cancer first-line monotherapy

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer

and Patient has not had chemotherapy for their disease in the palliative setting

and Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC

and For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain

and Pembrolizumab to be used as monotherapy

and

There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 50% as determined by a validated test unless not possible to ascertain

or

There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 1% as determined by a validated test unless not possible to ascertain

and Chemotherapy is determined to be not in the best interest of the patient based on clinician assessment

and Patient has an ECOG 0-2

and Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

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

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 – email: customerservice@health.govt.nz

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:

Pembrolizumab - continued

Renewal — non-small cell lung cancer first line monotherapy

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

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. 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
 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

and
 No evidence of disease progression

and
 The treatment remains clinically appropriate and patient is benefitting from treatment

and
 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent)

and
 Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

Initial application — non-small cell lung cancer first-line combination therapy

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer

and
 The patient has not had chemotherapy for their disease in the palliative setting

and
 Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC

and
 For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain

and
 Pembrolizumab to be used in combination with platinum-based chemotherapy

and
 Patient has an ECOG 0-2

and
 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

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

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 – email: customerservice@health.govt.nz

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:

Pembrolizumab - *continued*

Renewal — non-small cell lung cancer first line combination therapy

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

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> Patient's disease has had a complete response to treatment or <input type="checkbox"/> Patient's disease has had a partial response to treatment or <input type="checkbox"/> Patient has stable disease
and
<input type="checkbox"/> Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period
and
<input type="checkbox"/> No evidence of disease progression
and
<input type="checkbox"/> The treatment remains clinically appropriate and patient is benefitting from treatment
and
<input type="checkbox"/> Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent)
and
<input type="checkbox"/> Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

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 – email: customerservice@health.govt.nz

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:

Pembrolizumab - continued

Initial application — breast cancer, advanced

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment

or

Patient has recurrent or de novo unresectable, inoperable locally advanced triple-negative breast cancer (that does not express ER, PR or HER2 IHC3+ or ISH+ [including FISH or other technology])

or

Patient has recurrent or de novo metastatic triple-negative breast cancer (that does not express ER, PR or HER2 IHC3+ or ISH+ [including FISH or other technology])

and

Patient is treated with palliative intent

and

Patient's cancer has confirmed PD-L1 Combined Positive Score (CPS) is greater than or equal to 10

and

Patient has received no prior systemic therapy in the palliative setting

and

Patient has an ECOG score of 0–2

and

Pembrolizumab is to be used in combination with chemotherapy

and

Baseline measurement of overall tumour burden is documented clinically and radiologically

and

Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

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 – email: customerservice@health.govt.nz

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:

Pembrolizumab - continued

Renewal — breast cancer, advanced

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

Applications from any relevant practitioner. Approvals valid for 6 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

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

and

- Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent)

and

- Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

Initial application — head and neck squamous cell carcinoma

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)

- Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment

or

- Patient has recurrent or metastatic head and neck squamous cell carcinoma of mucosal origin (excluding nasopharyngeal carcinoma) that is incurable by local therapies

and

- Patient has not received prior systemic therapy in the recurrent or metastatic setting

and

- Patient has a positive PD-L1 combined positive score (CPS) of greater than or equal to 1

and

- Patient has an ECOG performance score of 0-2

and

- Pembrolizumab to be used in combination with platinum-based chemotherapy

or

- Pembrolizumab to be used as monotherapy

and

- Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

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 – email: customerservice@health.govt.nz

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:

Pembrolizumab - continued

Renewal — head and neck squamous 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

Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent)

and

Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

Initial application — MSI-H/dMMR advanced colorectal cancer

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)

Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment

or

Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer

or

Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer

and

Patient is treated with palliative intent

and

Patient has not previously received funded treatment with pembrolizumab

and

Patient has an ECOG performance score of 0-2

and

Baseline measurement of overall tumour burden is documented clinically and radiologically

and

Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

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 – email: customerservice@health.govt.nz

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:

Pembrolizumab - continued

Renewal — MSI-H/dMMR advanced colorectal cancer

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

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

Prerequisites(tick boxes where appropriate)

No evidence of disease progression

and Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent)

and Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

Initial application — Urothelial carcinoma

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)

Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment

or

Patient has inoperable locally advanced (T4) or metastatic urothelial carcinoma

and Patient has an ECOG performance score of 0-2

and Patient has documented disease progression following treatment with chemotherapy

and Pembrolizumab to be used as monotherapy at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

Renewal — Urothelial carcinoma

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)

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 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent)

and Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

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 – email: customerservice@health.govt.nz

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:

Pembrolizumab - continued

Initial application — relapsed/refractory Hodgkin lymphoma

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)

<input type="checkbox"/>	Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment
or	
<input type="checkbox"/>	Patient has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy
and	
<input type="checkbox"/>	Patient is ineligible for autologous stem cell transplant
or	
<input type="checkbox"/>	Patient has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant
and	
<input type="checkbox"/>	Patient has not previously received funded pembrolizumab
and	
<input type="checkbox"/>	Pembrolizumab to be administered at doses no greater than 200 mg once every 3 weeks

Renewal — relapsed/refractory Hodgkin lymphoma

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 6 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/>	Patient has received a partial or complete response to pembrolizumab
and	
<input type="checkbox"/>	Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

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 – email: customerservice@health.govt.nz