

**SA2386 - Pembrolizumab**

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**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER** Reg No: .....

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**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](mailto:customerservice@health.govt.nz)

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**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

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**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

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**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

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**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)

- 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)

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**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)

<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 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
<input type="checkbox"/> 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
<input type="checkbox"/> Patient is treated with palliative intent
and
<input type="checkbox"/> Patient's cancer has confirmed PD-L1 Combined Positive Score (CPS) is greater than or equal to 10
and
<input type="checkbox"/> Patient has received no prior systemic therapy in the palliative setting
and
<input type="checkbox"/> Patient has an ECOG score of 0–2
and
<input type="checkbox"/> Pembrolizumab is to be used in combination with chemotherapy
and
<input type="checkbox"/> Baseline measurement of overall tumour burden is documented clinically and radiologically
and
<input type="checkbox"/> Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

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**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

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**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

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**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)

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**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
<b>or</b>	
<input type="checkbox"/>	Patient has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy
<b>and</b>	
<input type="checkbox"/>	Patient is ineligible for autologous stem cell transplant
<b>or</b>	
<input type="checkbox"/>	Patient has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant
<b>and</b>	
<input type="checkbox"/>	Patient has not previously received funded pembrolizumab
<b>and</b>	
<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
<b>and</b>	
<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)

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