

## SA2631 - Pembrolizumab

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

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**Pembrolizumab**

**Initial application — stage III or IV resectable melanoma - neoadjuvant**  
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)

- The individual has resectable stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note)
- and  The individual has not received prior funded systemic treatment in the perioperative setting for their stage IIIB, IIIC, IIID or IV melanoma
- and  Treatment must be prior to complete surgical resection
- and  Pembrolizumab must be administered as monotherapy
- and  The individual has ECOG performance score 0-2
- and  Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent)

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

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**Pembrolizumab - continued**

**Renewal — stage III or IV resectable melanoma - neoadjuvant**

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)

|   |
|---|
| <input type="checkbox"/> The individual has received neoadjuvant treatment with an immune checkpoint inhibitor<br><b>and</b><br><input type="checkbox"/> The individual meets initial application criteria for pembrolizumab for stage III or IV resected melanoma – adjuvant   |
| or  |
| <input type="checkbox"/> The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor<br><b>and</b><br><input type="checkbox"/> The individual meets renewal criteria for pembrolizumab for stage III or IV resected melanoma – adjuvant  |
| or  |
| <input type="checkbox"/> The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor<br><b>and</b><br><input type="checkbox"/> The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV<br><b>and</b><br><input type="checkbox"/> The individual meets initial application criteria for pembrolizumab for unresectable or metastatic melanoma              |
| or  |
| <input type="checkbox"/> The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor<br><b>and</b><br><input type="checkbox"/> The individual has received treatment with an immune checkpoint inhibitor for unresectable or metastatic melanoma<br><b>and</b><br><input type="checkbox"/> The individual meets renewal criteria for pembrolizumab for unresectable or metastatic melanoma |

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 either 13 weeks after resection (primary or lymphadenectomy) or 13 weeks prior to the scheduled date of the resection (primary or lymphadenectomy)

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**Pembrolizumab - continued**

**Initial application — stage III or IV resected melanoma - adjuvant**

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"/> | The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a)  |
| <b>and</b>               | <input type="checkbox"/>  |
| <input type="checkbox"/> | Adjuvant treatment with pembrolizumab is required   |
| <b>and</b>               | <input type="checkbox"/>  |
| <input type="checkbox"/> | The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma               |
| <b>and</b>               | <input type="checkbox"/>  |
| <input type="checkbox"/> | Treatment must be in addition to complete surgical resection  |
| <b>and</b>               | <input type="checkbox"/>  |
| <input type="checkbox"/> | Treatment must be initiated within 13 weeks of complete surgical resection, unless delay is necessary due to post-surgery recovery (see note b) |
| <b>and</b>               | <input type="checkbox"/>  |
| <input type="checkbox"/> | Pembrolizumab must be administered as monotherapy   |
| <b>and</b>               | <input type="checkbox"/>  |
| <input type="checkbox"/> | The individual has ECOG performance score 0-2   |
| <b>and</b>               | <input type="checkbox"/>  |
| <input type="checkbox"/> | Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent)  |

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.**

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**Pembrolizumab - continued**

**Renewal — stage III or IV resected melanoma - adjuvant**

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)

No evidence of disease recurrence  
**and**  Pembrolizumab must be administered as monotherapy  
**and**  Pembrolizumab to be administered at a fixed dose of 200 mg every three weeks (or equivalent) for a maximum of 12 months total treatment course, including any systemic neoadjuvant treatment  
**and**  Treatment to be discontinued at signs of disease recurrence or at completion of 12 months total treatment course (equivalent to 18 cycles at a dose of 200 mg every 3 weeks), including any systemic neoadjuvant treatment

or

The individual has received adjuvant treatment with an immune checkpoint inhibitor  
**and**  The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV  
**and**  The individual meets initial application criteria for pembrolizumab for unresectable or metastatic melanoma

or

The individual has received adjuvant treatment with an immune checkpoint inhibitor  
**and**  The individual has received treatment with an immune checkpoint inhibitor for unresectable or metastatic melanoma  
**and**  The individual meets renewal criteria for pembrolizumab for unresectable or metastatic melanoma

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**Pembrolizumab - continued**

**Initial application — unresectable or metastatic melanoma**

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"/> | The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV |   |
| <b>and</b>               | <input type="checkbox"/>   | Baseline measurement of overall tumour burden is documented clinically and radiologically   |
| <b>and</b>               | <input type="checkbox"/>   | The individual has ECOG performance score of 0-2  |
| <b>and</b>               | <input type="checkbox"/>   | The individual has not received funded nivolumab  |
| <b>or</b>                | <input type="checkbox"/>   | The individual has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance |
| <b>and</b>               | <input type="checkbox"/>   | The cancer did not progress while the individual was on nivolumab   |
| <b>and</b>               | <input type="checkbox"/>   | The individual has been diagnosed in the metastatic or unresectable stage III or IV setting   |
| <b>or</b>                | <input type="checkbox"/>   | The individual did not receive treatment in the perioperative setting with a PD-1/PD-L1 inhibitor   |
| <b>or</b>                | <input type="checkbox"/>   | The individual received treatment in the perioperative setting with a PD-1/PD-L1 inhibitor  |
| <b>and</b>               | <input type="checkbox"/>   | The individual did not experience disease recurrence while on treatment with that PD-1/PD-L1 inhibitor  |
| <b>and</b>               | <input type="checkbox"/>   | The individual did not experience disease recurrence within six months of completing perioperative treatment with a PD-1/PD-L1 inhibitor                                |

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**Pembrolizumab** - *continued*

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

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)

- 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

**and**

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

**or**

- The individual has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression
- and**
- The individual has signs of disease progression
- and**
- Disease has not progressed during previous treatment with pembrolizumab

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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 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"/> | The individual has been on treatment for more than 24 months   |
| <b>and</b>               |  |
| <input type="checkbox"/> | The individual's disease has had a complete response to treatment  |
| <b>or</b>                |  |
| <input type="checkbox"/> | The individual's disease has had a partial response to treatment   |
| <b>or</b>                |  |
| <input type="checkbox"/> | The individual has stable disease  |
| <b>and</b>               |  |
| <input type="checkbox"/> | Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period |
| <b>or</b>                |  |
| <input type="checkbox"/> | The individual has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression                  |
| <b>and</b>               |  |
| <input type="checkbox"/> | The individual has signs of disease progression  |
| <b>and</b>               |  |
| <input type="checkbox"/> | 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, ROS-1 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, ROS-1 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)

|  |
|--|
| <input type="checkbox"/> Patient's disease has had a complete response to treatment<br><b>or</b><br><input type="checkbox"/> Patient's disease has had a partial response to treatment<br><b>or</b><br><input type="checkbox"/> Patient has stable disease |
| <b>and</b>   |
| <input type="checkbox"/> Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period  |
| <b>and</b>   |
| <input type="checkbox"/> No evidence of disease progression  |
| <b>and</b>   |
| <input type="checkbox"/> The treatment remains clinically appropriate and patient is benefitting from treatment  |
| <b>and</b>   |
| <input type="checkbox"/> Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent)  |
| <b>and</b>   |
| <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)  |

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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)

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.

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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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Reg No: .....      First Names: .....      First Names: .....

Name: .....      Surname: .....      Surname: .....

Address: .....      DOB: .....      Address: .....

.....      Address: .....      .....

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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)

|  |
|--|
| <input type="checkbox"/> Patient's disease has had a complete response to treatment<br><b>or</b><br><input type="checkbox"/> Patient's disease has had a partial response to treatment<br><b>or</b><br><input type="checkbox"/> Patient has stable disease |
| <b>and</b>   |
| <input type="checkbox"/> No evidence of disease progression  |
| <b>and</b>   |
| <input type="checkbox"/> Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent)   |
| <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)   |

**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)

|   |
|---|
| <input type="checkbox"/> Individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment<br><b>or</b>  |
| <input type="checkbox"/> Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer<br><b>or</b><br><input type="checkbox"/> Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer |
| <b>and</b>  |
| <input type="checkbox"/> Individual is treated with palliative intent   |
| <b>and</b>  |
| <input type="checkbox"/> Individual has not previously received funded treatment with pembrolizumab for MSI-H/dMMR advanced colorectal cancer   |
| <b>and</b>  |
| <input type="checkbox"/> Individual has an ECOG performance score of 0-2  |
| <b>and</b>  |
| <input type="checkbox"/> Baseline measurement of overall tumour burden is documented clinically and radiologically  |
| <b>and</b>  |
| <input type="checkbox"/> 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: .....

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

Reg No: .....      First Names: .....      First Names: .....

Name: .....      Surname: .....      Surname: .....

Address: .....      DOB: .....      Address: .....

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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)

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|  |                           |                               |
|--|---------------------------|-------------------------------|
| <b>APPLICANT</b> (stamp or sticker acceptable) | <b>PATIENT NHI:</b> ..... | <b>REFERRER</b> 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"/> | Individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment |
| <b>or</b>                |  |
| <input type="checkbox"/> | Individual has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy                          |
| <b>and</b>               |  |
| <input type="checkbox"/> | Individual is ineligible for autologous stem cell transplant   |
| <b>or</b>                |  |
| <input type="checkbox"/> | Individual has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant  |
| <b>and</b>               |  |
| <input type="checkbox"/> | Individual has not previously received funded pembrolizumab for relapsed/refractory Hodgkin lymphoma                 |
| <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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