**RS2154 - Pembrolizumab**


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Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Pembrolizumab

**INITIATION – stage III or IV resectable melanoma - neoadjuvant**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ 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)



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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Pembrolizumab *- continued*

**CONTINUATION – stage III or IV resectable melanoma - neoadjuvant**
Re-assessment required after 4 months

**Prerequisites** (tick boxes where appropriate)

❍ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

❍ The individual has received neoadjuvant treatment with an immune checkpoint inhibitor

**and**

❍ The individual meets initiation criteria for pembrolizumab for stage III or IV resected melanoma – adjuvant

**or**

❍ The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor

**and**

❍ The individual meets continuation criteria for pembrolizumab for stage III or IV resected melanoma – adjuvant

**or**

❍ The individual has received neoadjuvant and 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 initiation criteria for pembrolizumab for unresectable or metastatic melanoma

**or**

❍ The individual has received neoadjuvant and 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 continuation 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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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Pembrolizumab *- continued*

**INITIATION – stage III or IV resected melanoma - adjuvant**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a)

**and**

- ○ Adjuvant treatment with pembrolizumab 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 in addition to complete surgical resection

**and**

- ○ Treatment must be initiated within 13 weeks of complete surgical resection, unless delay is necessary due to post-surgery recovery (see note b)

**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)

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)



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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Pembrolizumab *- continued*

**CONTINUATION – stage III or IV resected melanoma - adjuvant**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ 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 initiation 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 continuation criteria for pembrolizumab for unresectable or metastatic melanoma



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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Pembrolizumab *- continued*

**INITIATION – unresectable or metastatic melanoma**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ 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 0-2

**and**

- ○ The individual has not received funded nivolumab

**or**

- ○ The individual 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 individual was on nivolumab

**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 perioperative setting with a PD-1/PD-L1 inhibitor

**or**

- ○ The individual received treatment in the perioperative setting with a PD-1/PD-L1 inhibitor

**and**

- ○ The individual did not experience disease recurrence while on treatment with that PD-1/PD-L1 inhibitor

**and**

- ○ 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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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Pembrolizumab *- continued*

**CONTINUATION – unresectable or metastatic melanoma, less than 24 months on treatment**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ 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

**CONTINUATION – unresectable or metastatic melanoma, more than 24 months on treatment**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ The individual has been on treatment for more than 24 months

**and**

- ○ 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 or clinical assessment following the most recent treatment period

**and**

- ○ The treatment remains clinically appropriate and the individual is benefitting from the treatment

**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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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Pembrolizumab *- continued*

**INITIATION – non-small cell lung cancer first-line monotherapy**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ 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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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Pembrolizumab *- continued*

**CONTINUATION – non-small cell lung cancer first-line monotherapy**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**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 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)

**INITIATION – non-small cell lung cancer first-line combination therapy**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ 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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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Pembrolizumab *- continued*

**CONTINUATION – non-small cell lung cancer first-line combination therapy**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**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 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)

**INITIATION – breast cancer, advanced**
Re-assessment required after 6 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ 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

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Pembrolizumab *- continued*

**CONTINUATION – breast cancer, advanced**
Re-assessment required after 6 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**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**

- ○ 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)

**INITIATION – head and neck squamous cell carcinoma**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ 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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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Pembrolizumab *- continued*

**CONTINUATION – head and neck squamous cell carcinoma**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**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**

- ○ 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)

**INITIATION – MSI-H/dMMR advanced colorectal cancer**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ Individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment
- **or**
  - ○ Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer
  - **or** ○ Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer
  - **and** ○ Individual is treated with palliative intent
  - **and** ○ Individual has not previously received funded treatment with pembrolizumab for MSI-H/dMMR advanced colorectal cancer
  - **and** ○ Individual 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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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Pembrolizumab *- continued*

**CONTINUATION – MSI-H/dMMR advanced colorectal cancer**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**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)

**INITIATION – Urothelial carcinoma**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ 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

**CONTINUATION – Urothelial carcinoma**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**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**

- ○ No evidence of disease progression

**and**

- ○ Pembrolizumab is to be used as monotherapy 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 that the above details are correct:

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

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Pembrolizumab *- continued*

**INITIATION – relapsed/refractory Hodgkin lymphoma**
Re-assessment required after 4 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

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

**or**

- ○ Individual has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy

  **and**

  ○ Individual is ineligible for autologous stem cell transplant

  **or**

  ○ Individual has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant

**and**

- ○ Individual has not previously received funded pembrolizumab for relapsed/refractory Hodgkin lymphoma

**and**

- ○ Pembrolizumab to be administered at doses no greater than 200 mg once every 3 weeks

**CONTINUATION – relapsed/refractory Hodgkin lymphoma**
Re-assessment required after 6 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ Patient has received a partial or complete response to pembrolizumab

**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 that the above details are correct:

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