RS2134 - Pembrolizumab

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

or

- ○ 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 that the above details are correct:

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

or

- ○ 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)

I confirm that the above details are correct:

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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

I confirm that the above details are correct:

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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

I confirm that the above details are correct:

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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

I confirm that the above details are correct:

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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

I confirm that the above details are correct:

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

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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

I confirm that the above details are correct:

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

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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

I confirm that the above details are correct:

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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

I confirm that the above details are correct:

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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: .....

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 *- 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: .....