

RS2185 - 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

PATIENT:

Name:

Name:

Ward:

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

PATIENT:

Name:

Name:

Ward:

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

PATIENT:

Name:

Name:

Ward:

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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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

PATIENT:

Name:

Ward: 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 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, 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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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 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, 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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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

PATIENT:

Name:

Ward: 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

PATIENT:

Name:

Ward: 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)

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PRESCRIBER

PATIENT:

Name:

Name:

Ward:

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: