RS2056 - 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 – unresectable or metastatic melanoma
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 metastatic or unresectable melanoma (excluding uveal) stage III or IV

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

and

- ○ The patient has ECOG performance score of 0-2

and

- ○ Patient has not received funded nivolumab

or

- ○ Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance

and

- ○ The cancer did not progress while the patient was on nivolumab

and

- ○ Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses

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 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

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

or

- ○ Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression

and

- ○ Patient has signs of disease progression

and

- ○ Disease has not progressed during previous treatment with pembrolizumab

I confirm that the above details are correct:

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

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

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 medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has been on treatment for more than 24 months

and

- ○ Patient's disease has had a complete response to treatment

  or

  ○ Patient's disease has had a partial response to treatment

  or

  ○ Patient has stable disease

  and

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

  and

  ○ The treatment remains clinically appropriate and the patient is benefitting from the treatment

or

- ○ Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression

  and

  ○ Patient has signs of disease progression

  and

  ○ Disease has not progressed during previous treatment with pembrolizumab

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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

I confirm that the above details are correct:

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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

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

or

- ○ Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer

or

- ○ Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer

and

- ○ Patient is treated with palliative intent

and

- ○ Patient has not previously received funded treatment with pembrolizumab

and

- ○ Patient has an ECOG performance score of 0-2

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

and

- ○ Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

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: .....

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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

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

or

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

  and

  ○ Patient is ineligible for autologous stem cell transplant

  or

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

and

- ○ Patient has not previously received funded pembrolizumab

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: .....