

RS2056 - Pembrolizumab

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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:

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PRESCRIBER

PATIENT:

Name: Name:

Ward: 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

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 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

PATIENT:

Name:

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

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

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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

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: