SA2386 - Pembrolizumab

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APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
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Pembrolizumab

Initial application — unresectable or metastatic melanoma
Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ 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

Renewal — unresectable or metastatic melanoma, less than 24 months on treatment

Current approval Number (if known):.....

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ 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 the above details are correct and that in signing this form I understand I may be audited.

Signed: ..... Date: .....
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Pembrolizumab *- continued*

Renewal — unresectable or metastatic melanoma, more than 24 months on treatment

Current approval Number (if known):.....

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ 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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Pembrolizumab *- continued*

Initial application — non-small cell lung cancer first-line monotherapy
Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ 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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Pembrolizumab *- continued*

Renewal — non-small cell lung cancer first line monotherapy

Current approval Number (if known):.....

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ 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)

Initial application — non-small cell lung cancer first-line combination therapy

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ 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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Pembrolizumab *- continued*

Renewal — non-small cell lung cancer first line combination therapy

Current approval Number (if known):.....

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ 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)

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Pembrolizumab *- continued*

Initial application — breast cancer, advanced
Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

☐ 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 the above details are correct and that in signing this form I understand I may be audited.

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

APPLICANT (stamp or sticker acceptable)

Reg No: .....

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Address: .....

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Pembrolizumab *- continued*

Renewal — breast cancer, advanced

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

- ☐ 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)

Initial application — head and neck squamous cell carcinoma

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

☐ 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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Pembrolizumab *- continued*

Renewal — head and neck squamous cell carcinoma

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ 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)

Initial application — MSI-H/dMMR advanced colorectal cancer

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ 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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Pembrolizumab *- continued*

Renewal — MSI-H/dMMR advanced colorectal cancer

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ 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)

Initial application — Urothelial carcinoma

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ 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

Renewal — Urothelial carcinoma

Current approval Number (if known):.....

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ 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 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)

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Pembrolizumab *- continued*

Initial application — relapsed/refractory Hodgkin lymphoma

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

☐ 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

Renewal — relapsed/refractory Hodgkin lymphoma

Current approval Number (if known):.....

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

☐ 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)

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