SA2631 - Pembrolizumab

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

Initial application — stage III or IV resectable melanoma - neoadjuvant
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)

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

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Pembrolizumab *- continued*

Renewal — stage III or IV resectable melanoma - neoadjuvant

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)

- ☐ The individual has received neoadjuvant treatment with an immune checkpoint inhibitor
  and
- ☐ The individual meets initial application 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 renewal 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 initial application 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 renewal 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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Pembrolizumab *- continued*

Initial application — stage III or IV resected melanoma - adjuvant
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)

- ☐ 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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Pembrolizumab *- continued*

Renewal — stage III or IV resected melanoma - adjuvant

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)

- ☐ 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 initial application 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 renewal criteria for pembrolizumab for unresectable or metastatic melanoma

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Pembrolizumab *- continued*

Initial application — unresectable or metastatic melanoma
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)

- ☐ 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 score of 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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Pembrolizumab *- continued*

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

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)

- ☐ 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

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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 relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ 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

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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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, 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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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, 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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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

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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)

- ☐ 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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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)

☐ 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

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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