RS2056 - 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.

| CRIBER | PATIENT: |
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| : | Name: |
| | NHI: |
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| | unresectable or metastatic melanoma |
| | ent required after 4 months s (tick boxes where appropriate) |
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| | scribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health spital. |
| O | 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 and | The patient has ECOG performance score of 0-2 |
| | O Patient has not received funded nivolumab |
| 0 | Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks |
| | of starting treatment due to intolerance |
| | The cancer did not progress while the patient was on nivolumab |
| and | |
| TINUATI | Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses ION – unresectable or metastatic melanoma, less than 24 months on treatment ent required after 4 months s (tick boxes where appropriate) |
| TINUATI ssessme equisites Pres | Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses ION – unresectable or metastatic melanoma, less than 24 months on treatment ent required after 4 months s (tick boxes where appropriate) |
| TINUATI ssessme equisites Pres | Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses ION – unresectable or metastatic melanoma, less than 24 months on treatment ent required after 4 months s (tick boxes where appropriate) scribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Healt spital. |
| TINUATI ssessme equisites Pres | Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses ION – unresectable or metastatic melanoma, less than 24 months on treatment ent required after 4 months is (tick boxes where appropriate) scribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Healt spital. O Patient's disease has had a complete response to treatment or |
| TINUATI ssessme equisites Pres | Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses ION – unresectable or metastatic melanoma, less than 24 months on treatment ent required after 4 months s (tick boxes where appropriate) scribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Healt epital. O Patient's disease has had a complete response to treatment O Patient's disease has had a partial response to treatment |
| TINUATI ssessme equisites Pres | Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses ION – unresectable or metastatic melanoma, less than 24 months on treatment ent required after 4 months is (tick boxes where appropriate) scribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Healt spital. O Patient's disease has had a complete response to treatment or |
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| TINUATI ssessme equisites Pres Hos | Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses ON - unresectable or metastatic melanoma, less than 24 months on treatment ent required after 4 months is (tick boxes where appropriate) Secribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Healt spital. O |
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| TINUATI ssessme equisites Hos | Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses ON - unresectable or metastatic melanoma, less than 24 months on treatment entrequired after 4 months is (tick boxes where appropriate) Society of the continued of the conti |
| TINUATI ssessme equisites Hos | Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses ION – unresectable or metastatic melanoma, less than 24 months on treatment ent required after 4 months is (tick boxes where appropriate) scribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health spital. O Patient's disease has had a complete response to treatment or O Patient's disease has had a partial response to treatment or O Patient has stable disease M Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period The treatment remains clinically appropriate and the patient is benefitting from the treatment |
| TINUATI ssessme equisites Hos | Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses ION – unresectable or metastatic melanoma, less than 24 months on treatment ent required after 4 months is (tick boxes where appropriate) scribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Healt spital. O Patient's disease has had a complete response to treatment or O Patient's disease has had a partial response to treatment or O Patient has stable disease Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period The treatment remains clinically appropriate and the patient is benefitting from the treatment |
| TINUATI ssessme equisites Hos | Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses ION – unresectable or metastatic melanoma, less than 24 months on treatment after equired after 4 months is (tick boxes where appropriate) scribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Healt spital. O Patient's disease has had a complete response to treatment or Patient has stable disease Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period The treatment remains clinically appropriate and the patient is benefitting from the treatment Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression Patient has signs of disease progression |
| TINUATI ssessme equisites Hos | Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses ION – unresectable or metastatic melanoma, less than 24 months on treatment after equired after 4 months is (tick boxes where appropriate) scribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health spital. O Patient's disease has had a complete response to treatment or Patient has stable disease Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period The treatment remains clinically appropriate and the patient is benefitting from the treatment Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression and Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression |

I confirm that the above details are correct:

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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 - continued | |
| CONTINUATION – unresectable or metastatic melanoma, more than 24 in Re-assessment required after 4 months Prerequisites (tick boxes where appropriate) | months on treatment |
| O Prescribed by, or recommended by a medical oncologist, or in accordance Hospital. | rdance with a protocol or guideline that has been endorsed by the Health NZ |
| Patient has been on treatment for more than 24 months and | |
| Patient's disease has had a complete response or Patient's disease has had a partial response or Patient has stable disease | |
| the most recent treatment period The treatment remains clinically appropriate and | determined by comparable radiologic or clinical assessment following the patient is benefitting from the treatment |
| Patient has previously discontinued treatment wit progression and Patient has signs of disease progression and | h pembrolizumab for reasons other than severe toxicity or disease |
| O Disease has not progressed during previous trea | tment with pembrolizumab |

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| PRES | SCRIE | BER | PATIENT: | |
|----------|-------|------------|---|---|
| Name | e: | | Name: | |
| Ward | : | | NHI: | |
| Pem | brol | izur | zumab - continued | |
| Re-a | ssess | men | - non-small cell lung cancer first-line monotherapy nent required after 4 months es (tick boxes where appropriate) | |
| (and | | | escribed by, or recommended by a medical oncologist or any relevant practitioner on the reco cordance with a protocol or guideline that has been endorsed by the Health NZ Hospital. | ommendation of a medical oncologist, or in |
| | and | 0 | Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer | |
| | and | 0 | Patient has not had chemotherapy for their disease in the palliative setting | |
| | and | \bigcirc | Patient has not received prior funded treatment with an immune checkpoint inhibitor for N | SCLC |
| | | 0 | For patients with non-squamous histology there is documentation confirming that the dise EGFR or ALK tyrosine kinase unless not possible to ascertain | ease does not express activating mutations of |
| | and | 0 | Pembrolizumab to be used as monotherapy | |
| | | or | O There is documentation confirming the disease expresses PD-L1 at a level greater validated test unless not possible to ascertain | than or equal to 50% as determined by a |
| | | | O There is documentation confirming the disease expresses PD-L1 at a level group by a validated test unless not possible to ascertain and | reater than or equal to 1% as determined |
| | | | O Chemotherapy is determined to be not in the best interest of the patient base | d on clinician assessment |
| | and | 0 | Patient has an ECOG 0-2 | |
| | | \circ | Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) | ent) for a maximum of 16 weeks |
| | and | 0 | Baseline measurement of overall tumour burden is documented clinically and radiological | lly |

Signed: Date:

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| PRES | CRIBER | PATIENT: |
|-------|---------------------------------|--|
| Name | : | |
| Ward: | | NHI: |
| Pem | brolizuı | mab - continued |
| Re-a | ssessmer equisites Preso | ON – non-small cell lung cancer first-line monotherapy It required after 4 months (tick boxes where appropriate) cribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in redance with a protocol or guideline that has been endorsed by the Health NZ Hospital. |
| | or | O Patient's disease has had a complete response to treatment O Patient's disease has had a partial response to treatment O Patient has stable disease |
| | and and and and and and | Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period No evidence of disease progression The treatment remains clinically appropriate and patient is benefitting from treatment Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks) |
| Re-a | ssessmer equisites Prese | non-small cell lung cancer first-line combination therapy It required after 4 months (tick boxes where appropriate) cribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in redance with a protocol or guideline that has been endorsed by the Health NZ Hospital. |
| | and and and and and and and and | Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer The patient has not had chemotherapy for their disease in the palliative setting Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC 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 Pembrolizumab to be used in combination with platinum-based chemotherapy Patient has an ECOG 0-2 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks Baseline measurement of overall tumour burden is documented clinically and radiologically |
| | | |

I confirm that the above details are correct:

Signed: Date:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

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 - continued | |
| CONTINUATION – non-small cell lung cancer first-line combination thera Re-assessment required after 4 months Prerequisites (tick boxes where appropriate) | ру |
| O Prescribed by, or recommended by a medical oncologist or any relevance accordance with a protocol or guideline that has been endorsed by tand | vant practitioner on the recommendation of a medical oncologist, or in he Health NZ Hospital. |
| Patient's disease has had a complete response to treatmen Patient's disease has had a partial response to treatmen Patient has stable disease | |
| Response to treatment in target lesions has been determined treatment period and No evidence of disease progression and The treatment remains clinically appropriate and patient is ber and Pembrolizumab to be used at a maximum dose of 200 mg ever and | |
| 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 relevance accordance with a protocol or guideline that has been endorsed by the and Patient is currently on treatment with pembrolizumab and met | he Health NZ Hospital. |
| Patient has recurrent or de novo unresectable, including or Patient has recurrent or de novo unresectable, including or ISH+ [including FISH or other technology] and Patient is treated with palliative intent and Patient's cancer has confirmed PD-L1 Combined Positive and Patient has received no prior systemic therapy in the palliand Patient has an ECOG score of 0–2 and Pembrolizumab is to be used in combination with chemicand Baseline measurement of overall tumour burden is document. | perable locally advanced triple-negative breast cancer (that does not g FISH or other technology]) negative breast cancer (that does not express ER, PR or HER2 IHC3+ e Score (CPS) is greater than or equal to 10 liative setting otherapy mented clinically and radiologically |
| 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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| PRESCRI | BER | PATIENT: | |
|-------------------|------------------------|---|----|
| Name: | | | |
| Ward: | | NHI: | |
| Pembro | lizur | ab - continued | |
| Re-asses Prerequi | smen sites Preso | I – breast cancer, advanced required after 6 months ick boxes where appropriate) bed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Heal | th |
| and | NZ H | spital. | |
| | | O Patient's disease has had a complete response to treatment | |
| | or | O Patient's disease has had a partial response to treatment | |
| | U | O Patient has stable disease | |
| and | O | No evidence of disease progression | |
| and | 0 | Response to treatment in target lesions has been determined by a comparable radiologic assessment following the most recent reatment period | |
| and | O | Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) | |
| | | Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks) | |
| Re-asses Prerequi | smen sites Preso | required after 4 months rick boxes where appropriate) bed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in ance with a protocol or guideline that has been endorsed by the Health NZ Hospital. | |
| or | 0 | Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment | |
| | and | Patient has recurrent or metastatic head and neck squamous cell carcinoma of mucosal origin (excluding nasopharyngeal carcinoma) that is incurable by local therapies Patient has not received prior systemic therapy in the recurrent or metastatic setting | |
| | an | Patient has a positive PD-L1 combined positive score (CPS) of greater than or equal to 1 | |
| | an | Patient has an ECOG performance score of 0-2 | |
| | | O Pembrolizumab to be used in combination with platinum-based chemotherapy or | |
| | | O Pembrolizumab to be used as monotherapy | |
| | an | 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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| Signed. | Date. |
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| PRES | CRIB | ER | | PATIENT: |
|------|------------------------------|-----------------------------|-----------------------------|---|
| Name | e: | | | |
| Ward | : | | | NHI: |
| Pem | broli | zun | nab | - continued |
| Re-a | ssessi equisi P | men i tes resc | t requ (tick b | ead and neck squamous cell carcinoma ired after 4 months oxes where appropriate) by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health I. Patient's disease has had a complete response to treatment |
| | | | \circ | Patient's disease has had a partial response to treatment |
| | | or | 0 | Patient has stable disease |
| | and and and |))) | Pemb Treat | orolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) ment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed 3 weeks) |
| Re-a | ssessi equisi | men i tes resc | t requ (tick b cribed | dMMR advanced colorectal cancer ired after 4 months oxes where appropriate) by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in with a protocol or guideline that has been endorsed by the Health NZ Hospital. |
| | Or (| С | Patie | nt is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment |
| | or | and and and and | | Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer Patient is treated with palliative intent Patient has not previously received funded treatment with pembrolizumab Patient has an ECOG performance score of 0-2 Baseline measurement of overall tumour burden is documented clinically and radiologically 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:

Signed: Date:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

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| PRESCRIBER | PATIENT: |
|--|---|
| Name: | Name: |
| Ward: | NHI: |
| Pembrolizumab - continued | |
| NZ Hospital. | or in accordance with a protocol or guideline that has been endorsed by the Health |
| No evidence of disease progression and Pembrolizumab to be used at a maximum dose of 200 r and Treatment with pembrolizumab is to cease after a total of every 3 weeks) | mg every three weeks (or equivalent) duration of 24 months from commencement (or equivalent of 35 cycles dosed |
| INITIATION – Urothelial carcinoma Re-assessment required after 4 months Prerequisites (tick boxes where appropriate) | |
| Prescribed by, or recommended by a relevant specialist or any accordance with a protocol or guideline that has been endors and | y relevant practitioner on the recommendation of a relevant specialist, or in ed by the Health NZ Hospital. |
| or | nd met all remaining criteria prior to commencing treatment |
| Patient has inoperable locally advanced (T4) or mand Patient has an ECOG performance score of 0-2 and Patient has documented disease progression followand Pembrolizumab to be used as monotherapy at a mand 16 weeks | |
| CONTINUATION – Urothelial carcinoma Re-assessment required after 4 months Prerequisites (tick boxes where appropriate) Prescribed by, or recommended by any relevant practitioner, of NZ Hospital. | or in accordance with a protocol or guideline that has been endorsed by the Health |
| O Patient's disease has had a complete response to or O Patient's disease has had a partial response to tree or O Patient has stable disease | |
| and | imum dose of 200 mg every three weeks (or equivalent) duration of 24 months from commencement (or equivalent of 35 cycles dosed |

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| PRES | CRIB | ER PATIENT: |
|-----------------|------------------------|---|
| Name: | | Name: |
| Ward: | | NHI: |
| Pemb | roli | zumab - continued |
| INITIA Re-as | ATIOI ssess quis | relapsed/refractory Hodgkin lymphoma nent required after 4 months es (tick boxes where appropriate) rescribed 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. Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment Patient has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy and Patient has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant or Patient has not previously received funded pembrolizumab and Pembrolizumab to be administered at doses no greater than 200 mg once every 3 weeks |
| Re-as | sess quis | TION – relapsed/refractory Hodgkin lymphoma nent required after 6 months es (tick boxes where appropriate) rescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health Z Hospital. |
| | and (| Patient has received a partial or complete response to pembrolizumab Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks) |
| | | |