RS2056 - Pembrolizumab

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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	
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 and Patient has metastatic or unresectable melanoma (excluding and Baseline measurement of overall tumour burden is document and The patient has ECOG performance score of 0-2 and Patient has not received funded nivolumab or	ed clinically and radiologically pproval for nivolumab and has discontinued nivolumab within 12 weeks
and Documentation confirming that the patient has been informed continued if their disease progresses	and acknowledges that funded treatment with pembrolizumab will not be
CONTINUATION – unresectable or metastatic melanoma, less than 24 m Re-assessment required after 4 months Prerequisites (tick boxes where appropriate) O Prescribed by, or recommended by a medical oncologist, or in acco	rdance with a protocol or guideline that has been endorsed by the Health NZ
Hospital.	
Patient's disease has had a complete response to to or Patient has stable disease	
And Response to treatment in target lesions has been determined treatment period and The treatment remains clinically appropriate and the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions has been determined to the particular treatment in target lesions have been determined to the particular treatment in target lesions have been determined to the particular treatment in target lesions have been determined to the particular treatment in target lesions have been determined to the particular treatment in target lesions have been determined to the particular treatment in target lesions have been determined to the particular treatment in target lesions have been determined to the particular treatment in target lesions have been determined to the particular treatment in target lesions have been determined to the partic	mined by comparable radiologic assessment following the most recent tient is benefitting from the treatment
Patient has previously discontinued treatment with pen and Patient has signs of disease progression and Disease has not progressed during previous treatment	brolizumab for reasons other than severe toxicity or disease progression with pembrolizumab

I confirm that the above details are correct:

Signed: Date:

PRESCRIBER	PATIENT:
Name:	Name:
Ward:	NHI:
Pembrolizumab - continued	
CONTINUATION – unresectable or metastatic melanoma, more than 24 Re-assessment required after 4 months Prerequisites (tick boxes where appropriate)	months on treatment
Prescribed by, or recommended by a medical oncologist, or in accommodate the Hospital.	ordance with a protocol or guideline that has been endorsed by the Health NZ
Patient has been on treatment for more than 24 months	
O Patient's disease has had a complete response or O Patient's disease has had a partial response or O Patient has stable disease	
the most recent treatment period and The treatment remains clinically appropriate and	the patient is benefitting from the treatment
Patient has previously discontinued treatment with 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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PRESCRIBER	PATIENT:
Name:	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) O Prescribed by, or recommended by a medical oncologist or any relevant	vant practitioner on the recommendation of a medical oncologist, or in
accordance with a protocol or guideline that has been endorsed by t	
Pembrolizumab to be used as monotherapy and There is documentation confirming the disease expressor validated test unless not possible to ascertain There is documentation confirming the disease expressor validated test unless not possible to ascertain There is documentation confirming the disease expressor by a validated test unless not possible to ascertain	tative setting the checkpoint inhibitor for NSCLC tion confirming that the disease does not express activating mutations of the PD-L1 at a level greater than or equal to 50% as determined by a the presses PD-L1 at a level greater than or equal to 1% as determined
and O Patient has an ECOG 0-2 and O Pembrolizumab to be used at a maximum dose of 200 mg ever and O Baseline measurement of overall tumour burden is documented.	

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Name: Ward: NHI: NHI: Pembrolizumab - continued CONTINUATION - non-small cell lung cancer first-line monotherapy Re-assessment required after required	PRES	CRIBER	PATIENT:
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. Patient's disease has had a complete 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 patient is benefitting from treatment and Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) 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. 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 Patient has not raceived 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 EGFR or ALK tyrosine kinase unless not possible to ascertain Pembrolizumab to be used in combination with platinum-based chemotherapy	Name:	:	
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. Patient's disease has had a complete response to treatment Patient's disease has had a partial response to treatment Patient has stable disease 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 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) 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 (lick 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. 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 Eor patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations and Pembrolizumab to be used in combination with platinum-based chemotherapy	Ward:		NHI:
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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. 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 EGFR or ALK tyrosine kinase unless not possible to ascertain Pembrolizumab to be used in combination with platinum-based chemotherapy			
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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 and For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations EGFR or ALK tyrosine kinase unless not possible to ascertain Pembrolizumab to be used in combination with platinum-based chemotherapy	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 EGFR or ALK tyrosine kinase unless not possible to ascertain Pembrolizumab to be used in combination with platinum-based chemotherapy		O	Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer
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 EGFR or ALK tyrosine kinase unless not possible to ascertain Pembrolizumab to be used in combination with platinum-based chemotherapy			The patient has not had chemotherapy for their disease in the palliative setting
For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations EGFR or ALK tyrosine kinase unless not possible to ascertain and Pembrolizumab to be used in combination with platinum-based chemotherapy			Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC
O Pembrolizumab to be used in combination with platinum-based chemotherapy		0	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		0	Pembrolizumab to be used in combination with platinum-based chemotherapy
O Patient has an ECOG 0-2		0	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		0	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		and	Baseline measurement of overall tumour burden is documented clinically and radiologically

I confirm that the above details are correct:

C:	D-1	
Signeg.	 Date:	
Cigiloa.	 Date.	

I confirm that the above details are correct:

Signed: Date:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

PRESCRIBER	PATIENT:
Name:	Name:
Ward:	NHI:
Pembrolizumab - continued	
CONTINUATION – non-small cell lung cancer first-line combination the Re-assessment required after 4 months Prerequisites (tick boxes where appropriate)	
accordance with a protocol or guideline that has been endorsed by	evant practitioner on the recommendation of a medical oncologist, or in the Health NZ Hospital.
Patient's disease has had a complete response to treatm Patient's disease has had a partial response to treatm Patient has stable disease	
and	d by comparable radiologic assessment following the most recent
and The treatment remains clinically appropriate and patient is b and Pembrolizumab to be used at a maximum dose of 200 mg e	
and	n of 24 months from commencement (or equivalent of 35 cycles dosed
accordance with a protocol or guideline that has been endorsed by	evant practitioner on the recommendation of a relevant specialist, or in v the Health NZ Hospital.
Patient is currently on treatment with pembrolizumab and me	et all remaining criteria prior to commencing treatment
Patient has recurrent or de novo unresectable, in express ER, PR or HER2 IHC3+ or ISH+ [includor	noperable locally advanced triple-negative breast cancer (that does not ing FISH or other technology]) e-negative breast cancer (that does not express ER, PR or HER2 IHC3+
and Patient is treated with palliative intent and Patient's cancer has confirmed PD-L1 Combined Posi and Patient has received no prior systemic therapy in the p	
and Patient has an ECOG score of 0–2 and Pembrolizumab is to be used in combination with cher	
Baseline measurement of overall tumour burden is do	cumented clinically and radiologically 00 mg every three weeks (or equivalent) for a maximum of 16 weeks

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 – breast cancer, advanced Re-assessment required after 6 months Prerequisites (tick boxes where appropriate) O Prescribed by, or recommended by any relevant practitioner, or in act NZ Hospital. and 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 and O No evidence of disease progression and	by a comparable radiologic assessment following the most recent
Treatment with pembrolizumab is to cease after a total duratic every 3 weeks) INITIATION – head and neck squamous cell carcinoma	on of 24 months from commencement (or equivalent of 35 cycles dosed
Re-assessment required after 4 months Prerequisites (tick boxes where appropriate)	
Prescribed by, or recommended by a relevant specialist or any relevant accordance with a protocol or guideline that has been endorsed by and	ant practitioner on the recommendation of a relevant specialist, or in the Health NZ Hospital.
O Patient is currently on treatment with pembrolizumab and met	all remaining criteria prior to commencing treatment
Patient has recurrent or metastatic head and neck square carcinoma) that is incurable by local therapies and Patient has not received prior systemic therapy in the reand Patient has a positive PD-L1 combined positive score (Cand Patient has an ECOG performance score of 0-2 and Pembrolizumab to be used in combination with place or Pembrolizumab to be used as monotherapy Pembrolizumab to be used as monotherapy	CPS) of greater than or equal to 1

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.

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

PRESCRIBER	PATIENT:
Name:	Name:
Ward:	NHI:
Pembrolizumab - continued	
CONTINUATION – MSI-H/dMMR advanced colorectal cancer Re-assessment required after 4 months Prerequisites (tick boxes where appropriate) Orecommended by any relevant practition NZ Hospital. and Orecommended by any relevant practition NZ Hospital. Pembrolizumab to be used at a maximum dose of and Orecommended by any relevant practition NZ Hospital.	oner, or in accordance with a protocol or guideline that has been endorsed by the Health f 200 mg every three weeks (or equivalent) total 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)	
accordance with a protocol or guideline that has been e	tor any relevant practitioner on the recommendation of a relevant specialist, or in endorsed by the Health NZ Hospital. nab and met all remaining criteria prior to commencing treatment
Patient has inoperable locally advanced (T4 and Patient has an ECOG performance score of and Patient has documented disease progressic and Pembrolizumab to be used as monotherapy 16 weeks	f 0-2
CONTINUATION – Urothelial carcinoma Re-assessment required after 4 months Prerequisites (tick boxes where appropriate) Oreginal Patient's disease has had a complete response or Oreginal Patient has stable disease and	
No evidence of disease progression and Pembrolizumab is to be used as monotherapy at a	a maximum dose of 200 mg every three weeks (or equivalent) total duration of 24 months from commencement (or equivalent of 35 cycles dosed

PRESCRIBER		PATIENT:
Name:		Name:
Ward:		NHI:
Pembrolizuma	b - continued	
Re-assessment re Prerequisites (tic	apsed/refractory Hodgkin lymphoma equired after 4 months ek boxes where appropriate) ed by, or recommended by a relevant specialist or any relevance with a protocol or guideline that has been endorsed by t	ant practitioner on the recommendation of a relevant specialist, or in he Health NZ Hospital.
or Pa	Patient is ineligible for autologous stem cell	phoma after two or more lines of chemotherapy transplant a and has previously undergone an autologous stem cell transplant ab
Re-assessment re Prerequisites (tice Prescrib NZ Hosp and Pa and Tree	atient has received a partial or complete response to pembro	cordance with a protocol or guideline that has been endorsed by the Health lizumab n of 24 months from commencement (or equivalent of 35 cycles dosed

I confirm that the above details are correct:

Signed: Date: