RS2154 - 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:
Pem	brol	lizun	nab	
Re-a	ssess	sment	stage III or IV resectable melanoma - neoadjuvant t required after 4 months (tick boxes where appropriate)	
(and			cribed by, or recommended by a relevant specialist or any relevant dance with a protocol or guideline that has been endorsed by the	ant practitioner on the recommendation of a relevant specialist, or in the Health NZ Hospital.
	and		The individual has resectable stage IIIB, IIIC, IIID or IV meland	ma (excluding uveal) (see note)
	and		The individual has not received prior funded systemic treatmer melanoma	at in the perioperative setting for their stage IIIB, IIIC, IIID or IV
	and	0	Treatment must be prior to complete surgical resection	
		0	Pembrolizumab must be administered as monotherapy	
	and	0	The individual has ECOG performance score 0-2	
	and	0	Pembrolizumab to be administered at a fixed dose of 200 mg e	every 3 weeks (or equivalent)

PRESCR	RIBER			PATIENT:
Name:				Name:
Ward:				NHI:
Pembro	olizumab	- continued		
Re-asses	ssment requ	stage III or IV resulting after 4 month poxes where approxes		oadjuvant
and				alist or any relevant practitioner on the recommendation of a relevant specialist, or in n endorsed by the Health NZ Hospital.
	and O			treatment with an immune checkpoint inhibitor pembrolizumab for stage III or IV resected melanoma – adjuvant
or	and O		·	and adjuvant treatment with an immune checkpoint inhibitor a for pembrolizumab for stage III or IV resected melanoma – adjuvant
or	and O and	The individual ha	as metastatic or unresecta	and adjuvant treatment with an immune checkpoint inhibitor stable melanoma (excluding uveal) stage III or IV pembrolizumab for unresectable or metastatic melanoma
or	and O and	The individual ha	as received treatment with	and adjuvant treatment with an immune checkpoint inhibitor th an immune checkpoint inhibitor for unresectable or metastatic melanoma a for pembrolizumab for unresectable or metastatic melanoma
b) Initiat	ting treatme	nt within 13 weeks		can Joint Committee on Cancer (AJCC) 8th Edition section means either 13 weeks after resection (primary or lymphadenectomy) or 13 weeks phadenectomy)

I confirm that the above details are correct:	
Signed:	Date:

PRES	SCRIBER		PATIENT:	
Name	ə:		Name:	
Ward	:		NHI:	
Pem	brolizur	mab - continued		
Re-a	ssessmen	stage III or IV resected melanoma - adjuvant t required after 4 months		
Prer	equisites	(tick boxes where appropriate)		
and		cribed by, or recommended by a relevant specialist or any relev rdance with a protocol or guideline that has been endorsed by t	ant practitioner on the recommendation of a relevant specialist, or in the Health NZ Hospital.	
	and	The individual has resected stage IIIB, IIIC, IIID or IV melanon	na (excluding uveal) (see note a)	
	and	Adjuvant treatment with pembrolizumab is required		
	and	The individual has not received prior funded systemic treatme	nt in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma	
		Treatment must be in addition to complete surgical resection		
	and	Treatment must be initiated within 13 weeks of complete surgi (see note b)	cal resection, unless delay is necessary due to post-surgery recovery	
	and	Pembrolizumab must be administered as monotherapy		
		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	:		7	
a) S	Stage IIIB,	IIIC, IIID or IV melanoma defined as per American Joint Comm	ittee on Cancer (AJCC) 8th Edition	
b) li	b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)			

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Signed.	Date:	
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PRES	CRIE	BER		PATIENT:
Name	e:			Name:
Ward	:			NHI:
Pem	broli	izumab	- continued	
Re-a	ssess	ment requ	stage III or IV resected melanoma - adjuvant uired after 4 months	
Prer	equis	ites (tick b	poxes where appropriate)	
and			by, or recommended by a relevant specialist or any relevant 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.
		and	No evidence of disease recurrence Pembrolizumab must be administered as monotherapy	
		and and	total treatment course, including any systemic neoadjuva	ence or at completion of 12 months total treatment course (equivalent to
	or			
		and and	The individual has received adjuvant treatment with an in. The individual has metastatic or unresectable melanoma. The individual meets initiation criteria for pembrolizumatic	a (excluding uveal) stage III or IV
	or			
		and on and	The individual has received adjuvant treatment with an in. The individual has received treatment with an immune comparison of the individual meets continuation criteria for pembrolizur	heckpoint inhibitor for unresectable or metastatic melanoma

PRESCRIBER	PATIENT:
Name:	Name:
Ward:	. NHI:
Pembrolizumab - continued	
INITIATION – unresectable or metastatic melanoma Re-assessment required after 4 months Prerequisites (tick boxes where appropriate)	
Prescribed by, or recommended by a relevant specialist or any releast accordance with a protocol or guideline that has been endorsed by and	evant practitioner on the recommendation of a relevant specialist, or in y the Health NZ Hospital.
The individual has metastatic or unresectable melanoma (exand Baseline measurement of overall tumour burden is documer and The individual has ECOG performance 0-2 and The individual has not received funded nivolumab or The individual has received an initial Special Au 12 weeks of starting treatment due to intolerance and The cancer did not progress while the individual	thority approval for nivolumab and has discontinued nivolumab within
and	rative setting with a PD-1/PD-L1 inhibitor

Signed: Date:

I confirm that the above details are correct:

Signed: Date:

	IBER		PATIENT:
Name:			Name:
Nard: NHI:			
Pembro	lizum	nab - continued	
CONTIN Re-asses	UATION ssment	N – unresectable or metast required after 4 months	atic melanoma, less than 24 months on treatment
Prerequi	isites (t	tick boxes where appropriate	
and	Prescr accord	ibed by, or recommended by lance with a protocol or guide	a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in eline that has been endorsed by the Health NZ Hospital.
		O The individual's o	disease has had a complete response to treatment
			disease has had a partial response to treatment
		The individual ha	as stable disease
	and	\sim	in target lesions has been determined by comparable radiologic assessment following the most recent
or	and	progression	viously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease
		O The individual has sign	s of disease progression
	and	\sim	essed during previous treatment with pembrolizumab
Prerequi	ssment isites (t Prescr	required after 4 months tick boxes where appropriate fibed by, or recommended by	atic melanoma, more than 24 months on treatment a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in eline that has been endorsed by the Health NZ Hospital.
Re-asses	Prescr accord	required after 4 months tick boxes where appropriate ibed by, or recommended by lance with a protocol or guide	a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in
Prerequi	Prescr accord	required after 4 months tick boxes where appropriate bed by, or recommended by dance with a protocol or guid. The individual has been on to	a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in eline that has been endorsed by the Health NZ Hospital.
Prerequi	Prescr accord	required after 4 months tick boxes where appropriate bed by, or recommended by dance with a protocol or guid. The individual has been on to	a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in eline that has been endorsed by the Health NZ Hospital.
Prerequi	Prescr accord	required after 4 months tick boxes where appropriate bed by, or recommended by dance with a protocol or guid. The individual has been on to the individual bed been on to the individual bed been on the individual bed bed belong the individual bed been on the individual bed bed belong the individual bed been on the individual bed been on the individual bed belong the individual belong the individu	a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in eline that has been endorsed by the Health NZ Hospital.
Prerequi	Prescr accord	required after 4 months tick boxes where appropriate bed by, or recommended by dance with a protocol or guid. The individual has been on to the individual for the i	a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in eline that has been endorsed by the Health NZ Hospital. reatment for more than 24 months dual's disease has had a complete response to treatment
Prerequi	Prescr accord	required after 4 months tick boxes where appropriate ribed by, or recommended by dance with a protocol or guide The individual has been on to The individual	a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in eline that has been endorsed by the Health NZ Hospital. The eatment for more than 24 months The eatment for more than 24 month
Prerequi	Prescr accord	required after 4 months tick boxes where appropriate block boxes b	a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in eline that has been endorsed by the Health NZ Hospital. The eatment for more than 24 months The eatment for more than 24 month
Prerequi	Prescr accord	required after 4 months tick boxes where appropriate block boxes block boxes block boxes where appropriate block boxes block b	a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in eline that has been endorsed by the Health NZ Hospital. The eatment for more than 24 months Itual's disease has had a complete response to treatment Itual's disease has had a partial response to treatment Itual has stable disease Itual has stable disease Itual has stable disease Itual has been determined by comparable radiologic or clinical assessment following reatment period Itual has stable disease has has been determined by comparable radiologic or clinical assessment following reatment period Itual has stable disease has has been determined by comparable radiologic or clinical assessment following reatment period Itual has stable disease has has been determined by comparable radiologic or clinical assessment following reatment period Itual has stable disease
Prerequi	Prescr accord	required after 4 months tick boxes where appropriate block boxes block boxes where appropriate block boxes where appropriate block boxes b	a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in eline that has been endorsed by the Health NZ Hospital. The eatment for more than 24 months Itual's disease has had a complete response to treatment Itual's disease has had a partial response to treatment Itual has stable disease Itual has stable disease Itual has stable disease Itual has been determined by comparable radiologic or clinical assessment following reatment period Itual has stable disease has has been determined by comparable radiologic or clinical assessment following reatment period Itual has stable disease has has been determined by comparable radiologic or clinical assessment following reatment period Itual has stable disease has has been determined by comparable radiologic or clinical assessment following reatment period Itual has stable disease
Prerequi	Prescr accord	required after 4 months tick boxes where appropriate block boxes b	a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in pline that has been endorsed by the Health NZ Hospital. Treatment for more than 24 months The disease has had a complete response to treatment that a partial response to treatment that has stable disease The disease has had a partial response to treatment that has stable disease The disease has had a partial response to treatment that a partial response to treatment that has stable disease The disease has had a partial response to treatment that has stable disease The disease has had a partial response to treatment that has stable disease The disease has had a partial response to treatment that has stable disease The disease has had a partial response to treatment that has stable disease The disease has had a partial response to treatment that has stable disease The disease has had a partial response to treatment that has stable disease.

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	the Health NZ Hospital.
Pembrolizumab to be used as monotherapy and There is documentation confirming the disease expressivalidated test unless not possible to ascertain There is documentation confirming the disease expressivalidated test unless not possible to ascertain There is documentation confirming the disease expressivalidated test unless not possible to ascertain	iative setting ne checkpoint inhibitor for NSCLC tion confirming that the disease does not express activating mutations of es PD-L1 at a level greater than or equal to 50% as determined by a expresses PD-L1 at a level greater than or equal to 1% as determined
and Patient has an ECOG 0-2 and Pembrolizumab to be used at a maximum dose of 200 mg ever and Baseline measurement of overall tumour burden is documented.	

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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:	
Ward:	NHI:
Pembrolizu	mab - continued
Prerequisites	ON – non-small cell lung cancer first-line monotherapy nt 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 ordance 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
or	O Patient's disease has had a partial response to treatment
	O 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)
0	Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)
Prerequisites	non-small cell lung cancer first-line combination therapy nt 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 ordance 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
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	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

I confirm that the above details are correct:

Signed: Date:

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)	ant practitioner on the recommendation of a medical oncologist, or in				
accordance with a protocol or guideline that has been endorsed by the 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 treatment period and No evidence of disease progression and The treatment remains clinically appropriate and patient is been and Pembrolizumab to be used at a maximum dose of 200 mg every	nent t by comparable radiologic assessment following the most recent efitting from treatment				
and	of 24 months from commencement (or equivalent of 35 cycles dosed				
INITIATION – breast cancer, advanced Re-assessment required after 6 months Prerequisites (tick boxes where appropriate) O 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. O Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment					
or	an remaining enterta prior to commencing treatment				
express ER, PR or HER2 IHC3+ or ISH+ [including	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+				
Patient is treated with palliative intent and Patient's cancer has confirmed PD-L1 Combined Positiv and Patient has received no prior systemic therapy in the pal and Patient has an ECOG score of 0–2 and Pembrolizumab is to be used in combination with chemo and Baseline measurement of overall tumour burden is docu and	therapy 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				

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 O Response to treatment in target lesions has been determined treatment period and O Pembrolizumab is to be used at a maximum dose of 200 mg eand	by a comparable radiologic assessment following the most recent
Treatment with pembrolizumab is to cease after a total duration every 3 weeks)	on of 24 months from commencement (or equivalent of 35 cycles dosed
accordance with a protocol or guideline that has been endorsed by to the protocol or guideline that has been endorsed by the protocol or guideline that has an endorsed by the protocol or guideline that has an endorsed by the protocol or guideline that has an endorsed by the protocol or guideline that has an endorsed by the protocol or guideline that has an endorsed by the protocol or guideline that has an endorsed by the protocol or guideline that has an endorsed by the protocol or guideline that has an endorsed by the protocol or guideline that has an endorsed by the protocol or gui	all remaining criteria prior to commencing treatment mous cell carcinoma of mucosal origin (excluding nasopharyngeal current or metastatic setting CPS) of greater than or equal to 1

I confirm that the above details are correct:

Signed: Date:

PRESCRIBER			PATIENT:				
Name	:						
Ward:				NHI:			
Pem	Pembrolizumab - continued						
Re-a	ssessr equisi P	men tes	t required to the tribect obspit.	head and neck squamous cell carcinoma uired after 4 months boxes where appropriate) d by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health al. Patient's disease has had a complete response to treatment Patient's disease has had a partial response to treatment Patient has stable disease evidence of disease progression abrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) extrement with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed by 3 weeks)			
Re-a	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	or	and and and and		O Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer Individual is treated with palliative intent Individual has not previously received funded treatment with pembrolizumab for MSI-H/dMMR advanced colorectal cancer Individual 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:

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I confirm that the above details are correct:

Signed: Date:

PATIENT:
NHI:
nab - continued
N – MSI-H/dMMR advanced colorectal cancer t required after 4 months (tick boxes where appropriate) pribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health ospital. No evidence of disease progression Pembrolizumab 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)
Urothelial carcinoma t required after 4 months (tick boxes where appropriate) bribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in dance 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 inoperable locally advanced (T4) or metastatic urothelial carcinoma Patient has an ECOG performance score of 0-2 Patient has documented disease progression following treatment with chemotherapy Pembrolizumab to be used as monotherapy at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks
N – Urothelial carcinoma t required after 4 months (tick boxes where appropriate) pribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health ospital. Patient's disease has had a complete response to treatment Patient's disease has had a partial response to treatment Patient has stable disease No evidence of disease progression Pembrolizumab is to be used as monotherapy 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)

PRESCRIPE	DATIFALE				
PRESCRIBER	PATIENT:				
Name:	Name:				
Ward:	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.					
O Individual is currently on treatment with pembrolizumab and n	net all remaining criteria prior to commencing treatment				
Individual has relapsed/refractory Hodgkin land Individual is ineligible for autologous stem of	ymphoma after two or more lines of chemotherapy ell transplant				
	oma and has previously undergone an autologous stem cell transplant				
and O Individual has not previously received funded pembrolizumab for relapsed/refractory Hodgkin lymphoma and					
O 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)					
O Prescribed by, or recommended by any relevant practitioner, or in an NZ Hospital.	ecordance with a protocol or guideline that has been endorsed by the Health				
O Patient has received a partial or complete response to pembro and	olizumab				
 Treatment with pembrolizumab is to cease after a total duration every 3 weeks) 	n of 24 months from commencement (or equivalent of 35 cycles dosed				

I confirm that the above details are correct:

Signed: Date: