# 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.

PRESCRIBER	PATIENT:
Name:	Name:
Ward:	NHI:

## Pembrolizumab

Re-as	sess	- unresectable or metastatic melanoma nent required after 4 months es (tick boxes where appropriate)	
and		escribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health N ospital.	Z
	( and	Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV	
	and (	D Baseline measurement of overall tumour burden is documented clinically and radiologically	
	and	The patient has ECOG performance score of 0-2	
		O Patient has not received funded nivolumab	
		Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance and	
		The cancer did not progress while the patient was on nivolumab	
	and (	Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses	
Prere	quisi	nent required after 4 months es (tick boxes where appropriate) escribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health N ospital.	Z
and			ן
		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	
		and 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	
	or		١
		O Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression and	
		O Patient has signs of disease progression and	
		$\bigcirc$ Disease has not progressed during previous treatment with pembrolizumab	

PRESCRIBER	PATIENT:	
Name:	Name:	
Ward:	NHI:	
Pembrolizumab - continued		
Re-assessment required after 4 m Prerequisites (tick boxes where a	appropriate)	eatment protocol or guideline that has been endorsed by the Health NZ
and O O O O O O O O O O O O O O O O O O O	on treatment for more than 24 months Patient's disease has had a complete response to treatmen Patient's disease has had a partial response to treatmen Patient has stable disease	
or And The tr Patier progres and Patier Patier Patier	nonse to treatment in target lesions has been determined b nost recent treatment period reatment remains clinically appropriate and the patient is l nt has previously discontinued treatment with pembrolizur ression nt has signs of disease progression	penefitting from the treatment
and O Disea	ase has not progressed during previous treatment with per	nbrolizumab

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 release accordance with a protocol or guideline that has been endorsed by the and	vant practitioner on the recommendation of a medical oncologist, or in the Health NZ Hospital.		
O Patient has locally advanced or metastatic, unresectable, non <b>and</b>	-small cell lung cancer		
O Patient has not had chemotherapy for their disease in the pall	iative setting		
	O Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC		
O For patients with non-squamous histology there is documenta EGFR or ALK tyrosine kinase unless not possible to ascertain	tion confirming that the disease does not express activating mutations of		
and O Pembrolizumab to be used as monotherapy and			
O There is documentation confirming the disease express validated test unless not possible to ascertain	es PD-L1 at a level greater than or equal to 50% as determined by a		
O There is documentation confirming the disease ex by a validated test unless not possible to ascertain and	presses PD-L1 at a level greater than or equal to 1% as determined		
	interest of the patient based on clinician assessment		
and O Patient has an ECOG 0-2			
O Pembrolizumab to be used at a maximum dose of 200 mg ever and	ery three weeks (or equivalent) for a maximum of 16 weeks		
Baseline measurement of overall tumour burden is documente	ed clinically and radiologically		

PRES	CRIBE	R	PATIENT:
Name	Name:		Name:
Ward			NHI:
Pem	broliz	un	nab - continued
Re-a	ssessn	nent	DN – non-small cell lung cancer first-line monotherapy t required after 4 months (tick boxes where appropriate)
( and			cribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in dance 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	<ul> <li>Patient's disease has had a partial response to treatment</li> <li>Patient has stable disease</li> </ul>
	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)
			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	ssessn	nent	non-small cell lung cancer first-line combination therapy t required after 4 months (tick boxes where appropriate)
( and	D Pr	esc	cribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in rdance 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
	and		For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain
	C	)	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
	(	)	Baseline measurement of overall tumour burden is documented clinically and radiologically

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PRESCRIBER	PATIENT:	
Name:	me: Name:	
Ward:		
Pembrolizumab - a	continued	
Re-assessment require Prerequisites (tick box O Prescribed by		
or or or P and Respor treatme and No evid and The treat and Pembro and Treatme	atient's disease has had a complete response to treatment atient's disease has had a partial response to treatment atient has stable disease use to treatment in target lesions has been determined by comparable radiologic assessment following the most recent int period lence of disease progression atment remains clinically appropriate and patient is benefitting from treatment blizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) ent with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed weeks)	
accordance w	d after 6 months	
or or and	is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment <ul> <li>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])</li> <li>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])</li> <li>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])</li> </ul>	
and P and P and P and P and B and	atient's cancer has confirmed PD-L1 Combined Positive Score (CPS) is greater than or equal to 10 atient has received no prior systemic therapy in the palliative setting atient has an ECOG score of 0–2 embrolizumab is to be used in combination with chemotherapy aseline measurement of overall tumour burden is documented clinically and radiologically embrolizumab 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:

Signed:		Date:	
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PRES	SCRIE	BER	PATIENT:
Name	lame: Name:		
Ward	:		
Pem	broli	izur	mab - continued
Re-a	issess	men	DN – breast cancer, advanced nt required after 6 months (tick boxes where appropriate)
( and			cribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health lospital.
		or	O Patient's disease has had a complete response to treatment
		or	$\sim$
	and		O Patient has stable disease
	and	0	No evidence of disease progression
	and	$\bigcirc$	Response to treatment in target lesions has been determined by a comparable radiologic assessment following the most recent treatment period
	and	Ο	Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent)
		0	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-a	issess equis	ites	head and neck squamous cell carcinoma ht required after 4 months (tick boxes where appropriate)
and		accoi	cribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in rdance 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
		an	O Patient has recurrent or metastatic head and neck squamous cell carcinoma of mucosal origin (excluding nasopharyngeal carcinoma) that is incurable by local therapies
			O Patient has not received prior systemic therapy in the recurrent or metastatic setting
		an	O Patient has a positive PD-L1 combined positive score (CPS) of greater than or equal to 1
		an an	O Patient has an ECOG performance score of 0-2
			O Pembrolizumab to be used in combination with platinum-based chemotherapy
			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

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PRESCRIBER		PATIENT:
Name:		Name:
Ward:		NHI:
Pembrolizuma	<b>b</b> - continued	
Re-assessment re Prerequisites (tick		cordance with a protocol or guideline that has been endorsed by the Health
and Patient's disease has had a complete response to treatment or or or 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 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) and O 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-assessment re Prerequisites (tick O Prescribe	I-H/dMMR advanced colorectal cancer equired after 4 months & boxes where appropriate) ed by, or recommended by a relevant specialist or any relevance with a protocol or guideline that has been endorsed by th	ant practitioner on the recommendation of a relevant specialist, or in the Health NZ Hospital.
or	<ul> <li>Patient has deficient mismatch repair (dMMR) or m</li> <li>Patient is treated with palliative intent</li> <li>Patient has not previously received funded treatment with</li> <li>Patient has an ECOG performance score of 0-2</li> <li>Baseline measurement of overall tumour burden is document</li> </ul>	hicrosatellite instability-high (MSI-H) metastatic colorectal cancer hicrosatellite instability-high (MSI-H) unresectable colorectal cancer

#### I confirm that the above details are correct:

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

PRES	RIBER PATIENT:
Name	Name:
Ward:	NHI:
Pem	rolizumab - continued
Re-a	NUATION – MSI-H/dMMR advanced colorectal cancer         essment required after 4 months         juisites (tick boxes where appropriate)         Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.         O       No evidence of disease progression
	Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) Ind 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-a	FION – Urothelial carcinoma         essment required after 4 months         uisites (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       Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment         or       O       Patient has inoperable locally advanced (T4) or metastatic urothelial carcinoma         and       O       Patient has an ECOG performance score of 0-2
Re-a	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  NUATION – Urothelial carcinoma essment required after 4 months uisites (tick boxes where appropriate)
and	Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

Signed:	Date:
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PRESCRIBER	PATIENT:
Name:	Name:
Ward:	NHI:

# Pembrolizumab - continued

INITIATION – relapsed/refractory Hodgkin lymphoma         Re-assessment required after 4 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
Patient has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy
O Patient is ineligible for autologous stem cell transplant
O Patient has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant
and O Patient has not previously received funded pembrolizumab
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 accordance with a protocol or guideline that has been endorsed by the He NZ Hospital.
Patient has received a partial or complete response to pembrolizumab
() Treatment with pembrolizumah is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed

Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)