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	smen	unresectable or metastatic melanoma It required after 4 months (tick boxes where appropriate)
and		Preso Hosp	cribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ ital.
		Ο	Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV
	and	Ο	Baseline measurement of overall tumour burden is documented clinically and radiologically
	and and	Ο	The patient has ECOG performance score of 0-2
		or	O Patient has not received funded nivolumab
			O 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	0	Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses
Prere) F		(tick boxes where appropriate) cribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ ital.
			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
		an	^d O Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent
		an	d The treatment remains clinically appropriate and the patient is benefitting from the treatment
	or		
		an	O Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression
		an	O Patient has signs of disease progression
			O 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 relevance with a protocol or guideline that has been endorsed by the and	vant practitioner on the recommendation of a medical oncologist, or in he Health NZ Hospital.
O Patient has locally advanced or metastatic, unresectable, non-	small cell lung cancer
O Patient has not had chemotherapy for their disease in the palli	ative setting
O Patient has not received prior funded treatment with an immun	e checkpoint inhibitor for NSCLC
O For patients with non-squamous histology there is documentat EGFR or ALK tyrosine kinase unless not possible to ascertain	ion 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 expresse 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	presses PD-L1 at a level greater than or equal to 1% as determined
	interest of the patient based on clinician assessment
and Patient has an ECOG 0-2	
O Pembrolizumab to be used at a maximum dose of 200 mg eve	ry three weeks (or equivalent) for a maximum of 16 weeks
Baseline measurement of overall tumour burden is documente	d clinically and radiologically

PRES	CRIBER	PATIENT:	
Name: Name:		Name:	
Ward:	Vard: NHI:		
Pem	brolizuı	mab - continued	
Re-a	ssessmer	DN – non-small cell lung cancer first-line monotherapy tt 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 rdance with a protocol or guideline that has been endorsed by the Health NZ Hospital.	
	or	$\hat{}$	
	or	 Patient's disease has had a partial response to treatment Patient has stable disease 	
	and O	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)	
Re-a	ssessmer	non-small cell lung cancer first-line combination therapy trequired after 4 months (tick boxes where appropriate)	
and	D Pres	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	
	0	Pembrolizumab to be used in combination with platinum-based chemotherapy	
	and O 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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PRES	SCRI	BER		PATIENT:
Name	ame: Name:			
Ward	ard: NHI:			
Pem	bro	lizur	ab - continued	
Re-a	asses requi:	smen sites Preso	required after 4 mo ck boxes where ap bed by, or recomm	
		or or	\sim	ease has had a complete response to treatment ease has had a partial response to treatment table disease
	and and	0	reatment period	nent in target lesions has been determined by comparable radiologic assessment following the most recent
	anc anc anc		embrolizumab to b	ease progression ains clinically appropriate and patient is benefitting from treatment be used at a maximum dose of 200 mg every three weeks (or equivalent) nbrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed
Re-a	asses requi:	smen sites Preso		onths
and	or	an an an an an an	 Patient express Patient or ISH+ Patient is trea Patient's cance Patient has rea Patient has are Patient has are Pembrolizumatic 	on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment has recurrent or de novo unresectable, inoperable locally advanced triple-negative breast cancer (that does not s ER, PR or HER2 IHC3+ or ISH+ [including FISH or other technology]) has recurrent or de novo metastatic triple-negative breast cancer (that does not express ER, PR or HER2 IHC3+ [including FISH or other technology] ated with palliative intent cer has confirmed PD-L1 Combined Positive Score (CPS) is greater than or equal to 10 eccived no prior systemic therapy in the palliative setting n ECOG score of 0–2 ab is to be used in combination with chemotherapy asurement of overall tumour burden is documented clinically and radiologically
			C Pembrolizuma	ab 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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PRESCRIBER	PATIENT:		
Name: Name:			
Ward:	Ward: NHI:		
Pembrolizu	mab - continued		
Re-assessme Prerequisites O Pres	ON – breast cancer, advanced nt required after 6 months s (tick boxes where appropriate) scribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health Hospital.		
and of or other or other	O Patient's disease has had a complete response to treatment O Patient's disease has had a partial response to treatment		
Re-assessme Prerequisites	head and neck squamous cell carcinoma nt required after 4 months s (tick boxes where appropriate) scribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in ordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.		
aı aı	Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment 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 Patient has a positive PD-L1 combined positive score (CPS) of greater than or equal to 1 Patient has an ECOG performance score of 0-2 Pembrolizumab to be used in combination with platinum-based chemotherapy Pembrolizumab to be used as monotherapy 		

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PRESCRIBER		PATIENT:	
Name:	ame: Name:		
Ward:	/ard:NHI:		
Pembrolizuma	b - continued		
Re-assessment re Prerequisites (tick		cordance with a protocol or guideline that has been endorsed by the Health	
and 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 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 relevan nce 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	 Patient has deficient mismatch repair (dMMR) or m Patient is treated with palliative intent Patient has not previously received funded treatment with Patient has an ECOG performance score of 0-2 Baseline measurement of overall tumour burden is document 	hicrosatellite instability-high (MSI-H) metastatic colorectal cancer hicrosatellite instability-high (MSI-H) unresectable colorectal cancer	

Signed: Date:

ame:
НІ:
rdance with a protocol or guideline that has been endorsed by the Health three weeks (or equivalent) f 24 months from commencement (or equivalent of 35 cycles dosed
practitioner on the recommendation of a relevant specialist, or in Health NZ Hospital.
remaining criteria prior to commencing treatment
urothelial carcinoma Itment with chemotherapy dose of 200 mg every three weeks (or equivalent) for a maximum of
rdance with a protocol or guideline that has been endorsed by the Health
nt be of 200 mg every three weeks (or equivalent) f 24 months from commencement (or equivalent of 35 cycles dosed
remaining criteria prior to commencing treatment urothelial carcinoma itment with chemotherapy dose of 200 mg every three weeks (or equivalent) for a maximum of redance with a protocol or guideline that has been endorsed by the H nt ee of 200 mg every three weeks (or equivalent)

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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 special accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.	ist, or in
or 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 and Patient is ineligible for autologous stem cell transplant 	
or	
O Patient has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell trans	nsplant
and O Patient has not previously received funded pembrolizumab 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 accordance with a protocol or guideline that has been endorse NZ Hospital.	d by the Health
O 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 cy	cles dosed

every 3 weeks)