#### 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:
:	Name:
	NHI:
brolizu	ımab
	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 and	Baseline measurement of overall tumour burden is documented clinically and radiologically
and	The patient has ECOG performance score of 0-2
O	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
and	The cancer did not progress while the patient was on nivolumab  Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not b continued if their disease progresses
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  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.
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
TINUATI ssessme equisites Prese 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 Patient's disease has had a partial response to treatment
TINUATI ssessme equisites Prese 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
TINUATI ssessme equisites Presidos 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 epital.  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 ind
TINUATI ssessme equisites Presidos 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 Presidos 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  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 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  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 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 Healtipital.  O Patient's disease has had a complete 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  O 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:

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

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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 accommended by a medical oncologist by a medical oncol	ordance with a protocol or guideline that has been endorsed by the Health NZ
Patient has been on treatment for more than 24 months	
Patient's disease has had a complete response or Patient's disease has had a partial response or Patient has stable disease	
Response to treatment in target lesions has been the most recent treatment period and The treatment remains clinically appropriate and	the patient is benefitting from the treatment
Patient has previously discontinued treatment wit progression  and Patient has signs of disease progression and	th pembrolizumab for reasons other than severe toxicity or disease
O Disease has not progressed during previous trea	trnent with pembrolizumab

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PRESCR	IBER		PATIENT:			
Name:			Name:			
Ward:			NHI:			
Pembro	lizur	mab - continued				
INITIATI Re-asse	ON – r	non-small cell lung cancer first-line monotherapy nt required after 4 months				
		(tick boxes where appropriate)				
and		cribed by, or recommended by a medical oncologist or any relevance with a protocol or guideline that has been endorsed by t	vant practitioner on the recommendation of a medical oncologist, or in the Health NZ Hospital.			
an	O	Patient has locally advanced or metastatic, unresectable, non-	-small cell lung cancer			
an	d	Patient has not had chemotherapy for their disease in the palli	iative setting			
	O Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC					
an	tion confirming that the disease does not express activating mutations of					
	Pembrolizumab to be used as monotherapy and					
	or	validated test unless not possible to ascertain	es PD-L1 at a level greater than or equal to 50% as determined by a			
		There is documentation confirming the disease ex by a validated test unless not possible to ascertain	expresses PD-L1 at a level greater than or equal to 1% as determined in			
	Chemotherapy is determined to be not in the best interest of the patient based on clinician assessment					
and Patient has an ECOG 0-2 and						
an	d O	Pembrolizumab to be used at a maximum dose of 200 mg ever Baseline measurement of overall tumour burden is documented				
		Dascinic incasurement of overall turnour burder is documented	od cirrically and radiologically			

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

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PRES	CRIBER	PATIENT:				
Name	:					
Ward:	Vard:NHI:					
Pem	brolizuı	mab - continued				
Re-a	ssessmer equisites Prese	N – non-small cell lung cancer first-line monotherapy t 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	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 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 equisites Prese	non-small cell lung cancer first-line combination therapy t 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		Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer				
	and and	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 of EGFR or ALK tyrosine kinase unless not possible to ascertain  Pembrolizumab to be used in combination with platinum-based chemotherapy				
	and and	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:

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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.

Name:
NHI:
continued
n-small cell lung cancer first-line combination therapy ed after 4 months xes where appropriate) y, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in
Patient's disease has had a complete response to treatment Patient's disease has had a partial response to treatment Patient has stable disease  The sease has had a partial response to treatment Patient has stable disease  The sease has had a partial response to treatment  The stable disease  The sease has had a partial response to treatment  The stable disease  The sease has had a partial response to treatment  The stable disease  The sease has had a partial response to treatment  The stable disease has had a partial response has been determined by comparable radiologic assessment following the mos
ent with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed 3 weeks)
eancer, advanced ed after 6 months exes where appropriate)  y, 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.  is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment
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])  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]  Patient is treated with palliative intent  Patient's cancer has confirmed PD-L1 Combined Positive Score (CPS) is greater than or equal to 10  Patient has received no prior systemic therapy in the palliative setting  Patient has an ECOG score of 0–2  Pembrolizumab is to be used in combination with chemotherapy  Baseline measurement of overall tumour burden is documented 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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PRESCRIBER		PATIENT:
Name: .		
Ward:		NHI:
Pembre	olizuı	mab - continued
Re-asse	ssmer iisites Prese	ON – breast cancer, advanced after 6 months (tick boxes where appropriate)  cribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health
and	NZ H	Hospital.
		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
ar ar	$\circ$	No evidence of disease progression
ar	0	Response to treatment in target lesions has been determined by a comparable radiologic assessment following the most recent treatment period
ar	$\circ$	Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent)
<b>.</b>	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-asse	ssmer iisites Prese	head and neck squamous cell carcinoma nt required after 4 months (tick boxes where appropriate)  cribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in redance with a protocol or guideline that has been endorsed by the Health NZ Hospital.
OI	0	Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment
	an	O Patient has not received prior systemic therapy in the recurrent or metastatic setting
	an	O Patient has an ECOG performance score of 0-2
	an	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
		—————————————————————————————————————

I confirm that the above details are correct:

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PRESCRIBER				PATIENT:
Name	Name:			Name:
Ward	:			NHI:
Pem	broli	zun	nab	- continued
Re-a	ssess <b>equis</b> i	men i <b>tes</b> Presc	No e	head and neck squamous cell carcinoma uired after 4 months boxes where appropriate)  It 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  brolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent)  tment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed y 3 weeks)
Re-a	ssess equisi	men i <b>tes</b> Presc	t requ (tick t	A/dMMR advanced colorectal cancer uired after 4 months boxes where appropriate)  B by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in e with a protocol or guideline that has been endorsed by the Health NZ Hospital.
and	or	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 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

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					
NZ Hospital.  No evidence of disease progression and Pembrolizumab to be used at a maximum dose of 200 mg and	in accordance with a protocol or guideline that has been endorsed by the Health g every three weeks (or equivalent) aration 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)  O Prescribed by, or recommended by a relevant specialist or any accordance with a protocol or guideline that has been endorsed	relevant practitioner on the recommendation of a relevant specialist, or in d by the Health NZ Hospital.				
Patient is currently on treatment with pembrolizumab and  Patient has inoperable locally advanced (T4) or me  and Patient has an ECOG performance score of 0-2  and Patient has documented disease progression follow and Pembrolizumab to be used as monotherapy at a ma 16 weeks	tastatic urothelial carcinoma				
CONTINUATION – Urothelial carcinoma Re-assessment required after 4 months Prerequisites (tick boxes where appropriate)  Or Patient's disease has had a complete response to treator Or Patient has stable disease					
and  No evidence of disease progression  and  Pembrolizumab is to be used as monotherapy at a maxim and  Treatment with pembrolizumab is to cease after a total du every 3 weeks)	num dose of 200 mg every three weeks (or equivalent) uration of 24 months from commencement (or equivalent of 35 cycles dosed				

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PRESCI	RIBER	R I	PATIENT:	
Name:		I	Name:	
Ward: .			NHI:	
Pembr	olizu	umab - continued		
INITIAT Re-ass	Pres acco	relapsed/refractory Hodgkin lymphoma ent required after 4 months es (tick boxes where appropriate)  escribed by, or recommended by a relevant specialist or any relevant cordance with a protocol or guideline that has been endorsed by the patient is currently on treatment with pembrolizumab and met a  Patient has relapsed/refractory Hodgkin lymphoma  Patient has relapsed/refractory Hodgkin lymphoma  Patient has relapsed/refractory Hodgkin lymphoma  Patient has not previously received funded pembrolizuma	ll remaining criteria prior to commencing treatment  homa after two or more lines of chemotherapy  ansplant  and has previously undergone an autologous stem cell transplant  b	
		O Pembrolizumab to be administered at doses no greater th	all 200 mg drice every 3 weeks	
CONTINUATION – relapsed/refractory Hodgkin lymphoma Re-assessment required after 6 months Prerequisites (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.				
and	ond	<ul> <li>Patient has received a partial or complete response to pembroli</li> <li>Treatment with pembrolizumab is to cease after a total duration every 3 weeks)</li> </ul>	zumab of 24 months from commencement (or equivalent of 35 cycles dosed	

I confirm that the above details are correct:

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